UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KENNETH GORDON, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. VANDA PHARMACEUTICALS INC., MIHAEL H. POLYMEROPOULOS, JAMES P. KELLY, GIAN PIERO REVERBERI, and THOMAS E. GIBBS, Defendants.	Civil Action No. 1:19-cv-01108-FB-LB CLASS ACTION AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

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Lead Plaintiff Teamsters Local Union No. 727 Pension Fund ("Lead Plaintiff" or "Plaintiff"), on behalf of itself and all other persons similarly situated, by Lead Plaintiff's undersigned attorneys, for Lead Plaintiff's amended complaint for violations of the federal securities laws against Defendants (defined below), alleges the following based upon personal knowledge as to Lead Plaintiff and Lead Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Lead Plaintiff's attorneys, which included, among other things, the review and analysis of: (i) Securities Exchange Commission ("SEC") filings made by Vanda Pharmaceuticals Inc. ("Vanda" or the "Company"); (ii) press releases, public statements, public letters, and other publications disseminated by, or concerning, Defendants; (iii) the allegations contained in pleadings filed in *U.S. ex rel. Gardner v. Vanda Pharmaceuticals*, No. 1:17-cv-00464 (APM) (D.D.C.) (the "Qui Tam Litigation"); (iv) the allegations contained in pleadings filed in *Vanda Pharmaceuticals, Inc. v. Food and Drug Administration, et al.*, No. 19-cv-301 (JDB) (D.D.C.) (the "FDA Litigation"); (v) interviews with former employees, including two of the Vanda former employees referenced in the pleadings in the Qui Tam Litigation; (vi) transcripts of investor conference calls with Vanda senior management; (vii) information posted on Vanda's corporate website; (viii) securities analyst reports concerning Vanda; (ix) news articles and media coverage concerning the events detailed herein; and (x) drug labels, approval information, and other materials made publicly available by the U.S. Food and Drug Administration ("FDA").[1]

[1] Lead Plaintiff's attorneys have Freedom of Information Act ("FOIA") requests pending before the FDA for documents relating to this case. In the event that these outstanding FOIA requests result in information that supports Lead Plaintiff's allegations, or broadens the scope of this complaint, Lead Plaintiff respectfully requests permission to amend this complaint pursuant to Federal Rule of Civil Procedure 15(a) within a reasonable period of time after such disclosure.

The investigation of Lead Plaintiff's attorneys is continuing, yet certain additional facts supporting these allegations are known only to Defendants or are exclusively within their custody or control. Lead Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers of the common stock of Vanda between November 4, 2015 and February 11, 2019, inclusive (the "Class Period"). Lead Plaintiff is asserting claims against Vanda and certain of its senior executives and/or directors under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule l0b-5 promulgated thereunder (17 C.F.R. §240.10b-5), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA").

2. Vanda is a biopharmaceutical company that markets and sells only two drugs: (i) Fanapt, which is FDA-approved to treat schizophrenia in adults; and (ii) Hetlioz, which is FDA-approved to treat Non-24, a rare circadian rhythm disorder that requires diagnosis by a doctor and occurs mostly, if not fully, in blind individuals ("Non-24"). During the Class Period, Vanda derived all of its revenue from sales of Fanapt and Hetlioz.

3. This class action stems from Defendants' materially false and misleading statements and omissions concerning a long-running and multifaceted off-label promotion scheme that Defendants undertook to sell Fanapt and Hetlioz during the Class Period. Drugs are promoted off-label when pharmaceutical companies market or promote to doctors to write prescriptions for symptoms or disorders that a drug is not FDA-approved to treat. Off-label promotion of drugs is illegal. Defendants not only knew about, or recklessly disregarded, this scheme – they were active and willing participants in it.

4. With respect to Fanapt, Vanda trained its sales representatives to promote the drug off-label in a variety of ways, including: (i) marketing Fanapt to treat mental disorders other than schizophrenia; (ii) focusing on akathisia, a side effect of antipsychotics, in an effort to obtain sales to non-schizophrenia patients; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-label sales; (v) targeting pediatric patients as part of the marketing efforts for Fanapt even though the drug is only FDA-approved for use by adults; (vi) presenting Fanapt as a first line treatment even though it is only FDA-approved as a second line treatment, meaning it should not be used unless a patient has tried another antipsychotic first; (vii) downplaying the extent and severity of QT prolongation, a serious and sometimes fatal side effect of Fanapt; and (viii) promoting that Fanapt can be administered once-daily even though it is only FDA-approved to be taken twice-daily.

5. With respect to Hetlioz, although Vanda repeatedly acknowledged that Non-24 occurs almost fully, if not exclusively, in blind individuals, the Company used its Fanapt sales representatives by at least November 2015 to promote Hetlioz to psychiatrists, even though psychiatrists are not known to treat many blind patients, let alone ones with Non-24. Indeed, Defendants focused their sales efforts for Hetlioz on sighted individuals who were having trouble sleeping – not those who received a doctor's diagnosis for Non-24, which can be tested for, but is exceedingly rare in sighted individuals. These efforts caused Hetlioz, which retailed for well over $100,000 per year during the Class Period, to be marketed off-label during the Class Period.

6. In addition to Fanapt and Hetlioz, this class action stems from Defendants' materially false and misleading statements and omissions concerning tradipitant, which was Vanda's most important drug in the clinical trial stage during the Class Period. Unbeknownst to investors, the FDA had informed Vanda in May 2018 that if the Company wanted to do a study of tradipitant in

humans for longer than three months – which was necessary for tradipitant to ultimately receive FDA approval – Vanda needed to conduct a nine-month non-rodent study to ensure that tradipitant is safe for humans.

7. If Vanda failed to do the required safety study, the FDA informed the Company that it would take the drastic step of imposing a clinical trial hold on tradipitant. A clinical trial hold is an order issued by the FDA to delay or suspend a drug trial. Clinical trial holds from the FDA are very rare. Despite being fully aware of the FDA's position by May 2018, Vanda nonetheless tried to conduct tradipitant studies lasting longer than three months. True to their word, in December 2018 the FDA issued clinical trial holds for tradipitant studies, placing the commercial future of tradipitant in serious jeopardy.

8. Thus, at all relevant times from May 2018 until the end of the Class Period, Defendants knew, or recklessly disregarded, that Vanda would not conduct the required safety test for tradipitant. Nonetheless, Defendants made numerous statements to investors regarding the progress of clinical trials for tradipitant without disclosing this material development.

9. When investors finally learned about Defendants' off-label promotion scheme for Fanapt and Hetlioz – which was first publicly revealed in a short seller report issued during the trading day on February 11, 2019 – and that Vanda refused to conduct a safety trial for tradipitant that was needed for it to ultimately received FDA approval – which was first publicly revealed when Vanda announced the filing of the FDA Litigation after the market closed on February 5, 2019 – Vanda's stock dropped precipitously on both occasions, causing damage to Lead Plaintiff and the Proposed Class (defined below).

JURISDICTION AND VENUE

10. Jurisdiction is conferred by §27 of the Exchange Act. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5.

11. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

12. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b). Dissemination of materially false and misleading information by Defendants occurred in this District.

13. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, telephonic communications, and the facilities of the national securities markets.

PARTIES

14. Lead Plaintiff Teamsters Local Union No. 727 Pension Fund purchased Vanda common stock during the Class Period, as set forth in its certification previously filed with the Court and incorporated herein by reference, and has been damaged thereby. *See* ECF No. 9-2.

15. Defendant Vanda is a biopharmaceutical company that licenses, clinically develops, markets and sells pharmaceutical drugs principally in the United States, including in New York. Vanda's common stock is traded on the NASDAQ securities exchange under the symbol "VNDA." According to Vanda's Form 10-Q for the fiscal quarter ended September 30, 2018 ("3Q18"), which was filed on November 7, 2018 (the "3Q18 Form 10-Q"), the Company had 52,449,800 shares of common stock outstanding as of October 25, 2018.

16. Defendant Mihael H. Polymeropoulos ("Polymeropoulos") co-founded Vanda in 2003 and has served as the Company's President, Chief Executive Officer ("CEO"), and a director on Vanda's board of directors since May 2003. Defendant Polymeropoulos is a psychiatrist who holds a degree in medicine from the University of Patras. Defendant Polymeropoulos is listed as one of the six members of Vanda's management team on Vanda's corporate website. According to the Form DEF14A filed by Vanda with the SEC on April 27, 2018 (the "4/27/18 Form DEF14A"),

defendant Polymeropoulos has been an executive officer of Vanda during his tenure as CEO. Defendant Polymeropoulos signed each of the Company's Forms 10-K and Forms 10-Q filed with the SEC during the Class Period. Defendant Polymeropoulos spoke at numerous Vanda investor conferences during the Class Period.

17. Defendant James P. Kelly ("Kelly") has served as the Company's Executive Vice President, Chief Financial Officer ("CFO), and Treasurer since December 2010. Defendant Kelly has worked in the biotechnology and pharmaceutical industry since 1991. Defendant Kelly is listed as one of the six members of Vanda's management team on Vanda's corporate website. According to the 4/27/18 Form DEF14A, defendant Kelly has been an executive officer of Vanda during his tenure as CFO. Defendant Kelly signed each of the Company's Forms 10-K and Forms 10-Q filed during the Class Period. Defendant Kelly spoke at numerous Vanda investor conferences during the Class Period.

18. Defendant Gian Piero Reverberi ("Reverberi") has served as the Company's Senior Vice President and Chief Commercial Officer ("CCO") since December 2015. Immediately before serving in this role, defendant Reverberi served as the Company's Senior Vice President and European General Manager from September 2015 to December 2015. Defendant Reverberi has spent a large portion of his career working in the biotechnology and pharmaceutical industry in the United States and Europe. Defendant Reverberi is listed as one of the six members of Vanda's management team on Vanda's corporate website. According to the 4/27/18 Form DEF14A, defendant Reverberi has been an executive officer of Vanda during his tenure as CCO. Defendant Reverberi spoke at numerous Vanda investor conferences during the Class Period.

19. Defendant Thomas E. Gibbs ("Gibbs") served as the Company's Senior Vice President and CCO from April 2015 until his departure in December 2015. Defendant Gibbs did not

previously work at Vanda before April 2015. Defendant Gibbs, who is currently the CCO of Optinose, Inc., a pharmaceutical company, has spent his career working in the biotechnology and pharmaceutical industry. According to the Form DEF14A filed by Vanda on April 29, 2015, defendant Gibbs was an executive officer of Vanda during his tenure as CCO. On December 21, 2015, Vanda filed a Form 8-K that, among other things, announced that defendant Gibbs had resigned from Vanda after only eight months as the Company's CCO (the "12/21/15 Form 8-K"). The 12/21/15 Form 8-K further stated, among other things, that because defendant Gibbs resigned, "he is not entitled to any severance or other post-termination benefits." Defendant Gibbs spoke during a Vanda investor conference during the Class Period.

20. Defendants Polymeropoulos, Kelly, Reverberi, and Gibbs are collectively referred to herein as the "Individual Defendants."

21. Vanda and the Individual Defendants are collectively referred to herein as "Defendants."

22. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via internal corporate documents (including the Company's operating plans, budgets and forecasts, and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and/or Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

23. It is appropriate to treat Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly

defined group of Defendants identified in ¶¶15-19 above. Each of the above officers of Vanda, by virtue of their high-level positions with the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein. Said Individual Defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

24. As officers and controlling persons of a publicly-held company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, and which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded stock would be based upon truthful and accurate information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

25. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature. Because of

their executive and managerial positions and/or Board membership with Vanda, the Individual Defendants each had access to the adverse undisclosed information about Vanda's business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Vanda and its business materially false and misleading.

26. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained herein.

27. Each Defendant is liable as a participant in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of Vanda common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding Vanda's financial reporting, business, operations and management and the intrinsic value of Vanda's common stock; and (ii) caused Lead Plaintiff and the Class to purchase Vanda publicly-traded stock at artificially inflated prices.

LEAD PLAINTIFF'S ALLEGATIONS ARE SUPPORTED BY INFORMATION PROVIDED BY FORMER EMPLOYEES

28. The two main individuals who provided facts and information in the Qui Tam Litigation are the following former employees of Vanda, both of whom provide information that strongly supports an inference that Defendants knew about, or recklessly disregarded, the off-label

promotion schemes for Fanapt and Hetlioz during the Class Period. Among other former Vanda employees interviewed by Lead Plaintiff's counsel, the allegations in this complaint that are ascribed to these two former employees have been independently verified. Thus, Lead Plaintiff's counsel did not solely rely on the allegations in pleadings filed in the Qui Tam Litigation for the allegations ascribed to these two former Vanda employees.

29. Richard Gardner ("Gardner") is the relator in the Qui Tam Litigation. Gardner worked at Vanda as a Regional Business Leader ("RBL") for the Mid-West region from November 16, 2015 until August 5, 2016. Gardner's region included Illinois, Wisconsin, Michigan, Ohio, Western Pennsylvania, West Virginia, and Indiana, where he oversaw approximately 10 sales representatives. Gardner believes that his departure from Vanda was due to his oft-stated reluctance to acquiesce to Vanda's off-label marketing promotion for Fanapt and Hetlioz.

30. Gardner initiated the Qui Tam Litigation on March 10, 2017, in the United States Court for the District of Columbia, pursuant to the federal False Claims Act, 31 U.S.C. §3729, and analogous statutes of twenty-five States. Gardner is currently prosecuting the Qui Tam Litigation against Vanda.

31. According to Gardner, RBLs were in charge of overseeing Vanda's 50 sales representatives for Fanapt, who were independent contractors hired through Publicis Touchpoint Solutions. Gardner states there were six RBLs during the Class Period, including himself and Bourgeois (defined below). According to Gardner, RBLs reported directly to Vanda's National Sales Director. Vanda's National Sales Director, who was David James ("James") from January 2014 until July 2016, reported directly to Vanda's CCO, meaning first defendant Gibbs and then defendant Reverberi. Vanda's CCO reported directly to Vanda's CEO, defendant Polymeropoulos. According to Gardner, the RBLs participated in weekly conference calls with James and Ramirez

(defined below) to discuss the marketing and promotion of Fanapt and Hetlioz, which defendant Polymeropoulos would periodically join. According to Gardner and Bourgeois, several times per year the RBLs would also attend in-person meetings with defendant Polymeropoulos and other Vanda senior executives in Washington, D.C.

32. Jeff Bourgeois ("Bourgeois") is also referenced in the Qui Tam Litigation. Bourgeois worked at Vanda as an RBL for the South-West region from November 2015 until June 2018. Bourgeois managed approximately nine Vanda sales representatives promoting Fanapt and Hetlioz in Louisiana, Arkansas and Texas from November 2015 until early 2017, when his territory changed to Texas and Oklahoma and the number of sales representatives he oversaw increased. Bourgeois believes that his departure from Vanda was due to his inability to meet Vanda's sales goals for Fanapt and Hetlioz by promoting the drugs on-label and his unwillingness to achieve these goals by promoting the drugs off-label.

33. Bourgeois affirmatively confirmed many of the allegations made by Gardner in the Qui Tam Litigation.

SUBSTANTIVE ALLEGATIONS

Vanda and Its Business

34. Vanda was co-founded by defendant Polymeropoulos in early 2003 after he left Novartis AG ("Novartis"). According to Vanda, the Company is focused on developing and commercializing novel therapies to address unmet medical conditions.

35. Vanda became a publicly-traded company on April 18, 2006. At this time, the Company had no FDA-approved drugs and only three products in the clinical trial stage. The first drug, iloperidone, obtained FDA approval before the Class Period and became known as Fanapt. According to its FDA label, Fanapt is approved to be sold to treat "adults with schizophrenia."

36. The second drug, VEC-162, or tasimelteon, also obtained FDA approval before the Class Period and became known as Hetlioz. According to its FDA label, Hetlioz is approved to treat "Non-24-Hour Sleep-Wake Disorder." Non-24 is a rare circadian rhythm disorder that occurs mostly, if not fully, in blind individuals due to their internal clocks not being synched with the light and dark cycles of the day because they cannot perceive light.

37. The third drug, VSF-173, failed to reach certain milestones under Vanda's license agreement with Novartis. As a result, the Company lost its license for VSF-173 on November 3, 2008.

38. In addition to the three drugs in Vanda's pipeline at the time the Company went public, since 2006 Vanda has entered into license agreements with more established pharmaceutical and biotechnology companies to develop and commercialize other drugs.

39. To that end, on April 12, 2012, Vanda entered into a license agreement with Eli Lilly and Company, which granted Vanda an exclusive worldwide license to develop and commercialize VLY-686, or tradipitant. During the Class Period, tradipitant was undergoing clinical trial testing for the purpose of obtaining FDA approval. Tradipitant is not currently FDA-approved.

40. By November 2015, the beginning of the Class Period, Vanda's portfolio of FDA-approved products consisted only of Fanapt and Hetlioz. Vanda did not receive FDA approval to sell any drugs other than Fanapt or Hetlioz during the Class Period.

41. By November 2015, Vanda had tradipitant, trichostatin A, and AQW051 undergoing clinical trial testing, none of which received FDA approval during the Class Period. By the end of the Class Period, in February 2019, Vanda was still undergoing clinical trial testing for tradipitant, trichostatin A, and AQW051. During the Class Period, Vanda only added one new drug to its clinical testing pipeline, CFTR, in March 2017.

42. Accordingly, during the Class Period, Vanda had only two FDA-approved drugs for sale – Fanapt and Hetlioz – and only three or four drugs in the clinical trial stage: tradipitant, trichostatin A, AQW051, and CFTR.

Vanda Derives Its Revenues Solely from Sales of Fanapt and Hetlioz

43. During the Class Period, Vanda derived revenue only through marketing and selling its two FDA-approved drugs, Fanapt and Hetlioz. According to the 2015 Form 10-K (defined below), Vanda's "net product sales consist of sales of HETLIOZ® and sales of Fanapt®." During the Class Period, there was no other contributors to Vanda's revenue other than sales of Fanapt and Hetlioz.

44. During FY15 (defined below), Vanda generated $109.925 million in revenue. Of this amount, sales of Fanapt consisted of $65.623 million in revenue and sales of Hetlioz consisted of $44.302 million in revenue.

45. During FY16 (defined below), Vanda generated $146.017 million in revenue. Of this amount, sales of Fanapt consisted of $74.346 million in revenue and sales of Hetlioz consisted of $71.671 million in revenue.

46. During FY17 (defined below), Vanda generated $165.083 million in revenue. Of this amount, sales of Fanapt consisted of $75.105 million in revenue and sales of Hetlioz consisted of $89.978 million in revenue.

47. During the fiscal year ended December 31, 2018 ("FY18"), Vanda generated $193.118 million in revenue. Of this amount, sales of Fanapt consisted of $77.283 million in revenue and sales of Hetlioz consisted of $115.835 million in revenue.

48. Accordingly, during the Class Period, marketing and selling Fanapt and Hetlioz was central to Vanda's operations and financial performance.

Vanda's Off-Label Promotion Schemes for Fanapt and Hetlioz Were Illegal

49. The term "off-label marketing" or "off-label promotion" refers to marketing or promoting a drug for an indication (*e.g.*, a disease or symptom) that it has never received FDA approval to treat.

50. By contrast, "on-label marketing" refers to marketing or promoting a drug for the indication or indications that the drug has received FDA approval to treat. In the case of Fanapt, that means schizophrenia in adults. In the case of Hetlioz, that means Non-24.

51. The FDA only approves drugs if they have been shown to be safe and effective for the specific indications that they are approved to treat.

52. The FDA does not regulate or control how FDA-approved drugs are prescribed by physicians once the drugs are marketed for sale by pharmaceutical companies. Thus, physicians are able, on their own volition, to prescribe drugs for off-label uses.

53. Nonetheless, Vanda cannot actively market or promote drugs off-label. Indeed, at all relevant times Vanda was required to comply with the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), and related FDA regulations, which prohibit pharmaceutical companies from introducing drugs into interstate commerce for any intended use that the FDA has not determined to be safe and effective. *See* §§505(a), 515 (a), 501(f)(1), and 301(a) and (d), of the FD&C Act, and 21 U.S.C. §§355(a), 360e(a), 351(f)(1)) and 331(a) and (d). Thus, Vanda was legally prohibited from engaging in off-label marketing or promotion during the Class Period.

54. The FD&C Act and the FDA also prohibit pharmaceutical companies, like Vanda, from introducing misbranded drugs into interstate commerce. *See* §§502(o), 501(f)(1), 513(f)(1), 515, and 301(a) and (d) of the FD&C Act and 21 U.S.C. §§352(o), 351(f)(1), 360c(f)(1), 360e and 331(a) and (d)).

55. Further, FDA guidance requires that if a physician inquires with a pharmaceutical company sales representative about potential off-label uses for a drug, the sales representative "should refer such questions to a medical/scientific officer or department . . . and the officer or department to which the referral is made should be separate from the sales and/or marketing department."

56. As explained herein, Vanda did not follow this FDA guidance during the Class Period. Instead, Vanda trained its sales representatives to market and sell Fanapt and Hetlioz off-label.

57. Off-label drug promotion has, in recent years, become the focus of health care fraud enforcement efforts by federal and state authorities under the False Claims Act ("FCA") and related state statutes. In FCA cases, which often start as *qui tam* whistleblower complaints, off-label promotion for non-medically approved indications allows federal and state authorities to recover large monetary settlements (including treble damages) from drug companies for each instance of off-label promotion.

58. Accordingly, at all relevant times during the Class Period, any and all off-label promotion or marketing engaged in by Vanda violated the FD&C Act, the FCA, and FDA guidance and regulations.

Vanda Obtains Its License to Market and Sell Fanapt Shortly Before the Class Period

59. In June 2004, before Vanda went public, the Company entered into a sublicense agreement with Novartis to develop and commercialize Fanapt on behalf of Novartis.

60. When Vanda went public in April 2006, the Company explained to investors that Vanda believed that Fanapt would be effective in treating schizophrenia and bipolar disorder. Specifically, the Company stated in the Form 424B4 prospectus provided to investors, in pertinent part, that:

> ***In addition to schizophrenia, we believe iloperidone may be effective in treating bipolar disorder. Most of the approved atypical antipsychotics have received approval for bipolar disorder subsequent to commercialization for the treatment of schizophrenia***. Iloperidone is ready for an initial Phase II trial in bipolar disorder.[2]

61. The reason why Vanda sought to receive FDA approval for Fanapt to treat both bipolar disorder and schizophrenia is because most antipsychotics – meaning the drugs that Fanapt would directly compete with – are indicated for treating multiple related mental illnesses.

62. In addition, bipolar disorder is more than twice as prevalent in the United States as schizophrenia. This means that obtaining an indication for bipolar disorder would vastly expand the pool of potential patients who could use Fanapt on-label.

63. Thus, if Fanapt could only obtain approval for treating schizophrenia, it would be at a significant competitive disadvantage.

64. Notwithstanding the importance of getting FDA approval to treat bipolar disorder, Vanda only submitted a new drug application ("NDA") for Fanapt to treat only schizophrenia, and not bipolar disorder or any other mental disorder. According to Vanda's Form 10-Q dated May 11, 2009, Vanda submitted the NDA for Fanapt on September 27, 2007.

65. In May 2009, the FDA approved Fanapt to treat schizophrenia in adults – not to treat bipolar disorder, or any other mental illness, or even schizophrenia in adolescents or children. For this reason, Fanapt's FDA label states that it is approved to treat "adults with schizophrenia."

66. Fanapt's FDA label also explains that Fanapt was approved as a second line treatment, which defendant Polymeropoulos acknowledged during the 6/9/16 Conference (defined below) and the 3/21/17 Conference (defined below). This meant that Fanapt was only supposed to be prescribed by a doctor if a different antipsychotic had already been used by a patient and was shown to be ineffective or poorly tolerated.

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[2] Unless stated otherwise, all emphasis is added.

67. The reason the FDA approved Fanapt as a second line treatment was because Fanapt users have a serious risk of developing QT prolongation, which is a side effect that can cause torsade de pointes type arrhythmia, which can result in sudden death. For this reason, Fanapt's FDA label contains a black box warning and states that other antipsychotics should be tried first.

68. A black box warning appears on FDA labels to alert patients and doctors about serious adverse effects, or life-threatening risks, for a particular drug. According to the FDA, a black box warning is the most serious drug warning that the FDA can impose on a drug. At all relevant times, Fanapt had a black box warning due to its risk of causing QT prolongation.

69. In addition, Fanapt was approved by the FDA for a "recommended target dosage" of "12 to 24 mg/day administered twice daily." Fanapt's requirement to be taken twice-daily made it unlike most other antipsychotics, which are indicated by the FDA for once-daily treatment. The reason why most antipsychotics have a once-daily formulation is because patients with mental disorders have difficulties taking their medicine on a routine schedule. Prescribing mentally ill patients medicine that only requires being taken once a day increases the chances that the patient will stick with treatment.

70. After Fanapt received FDA approval, Vanda and Novartis entered into an amended sublicense agreement in October 2009 that gave Novartis exclusive commercialization rights to Fanapt. Thus, as of October 2009, Novartis was responsible for selling and marketing Fanapt in the United States. In return, Vanda received royalty payments from Novartis on sales of Fanapt.

71. In May 2014, Vanda commenced arbitration against Novartis related to the licensing of Fanapt. In December 2014, Vanda entered into a settlement agreement with Novartis and dismissed the arbitration proceeding.

72. Under the terms of the settlement agreement, *inter alia*, Vanda obtained the rights to market and sell Fanapt in the United States. Vanda also obtained a license to develop AQW051.

73. Accordingly, while Vanda began marketing and selling Fanapt in the United States for the first time in early 2015, Fanapt had been an FDA approved drug and was sold by Novartis since May 2009.

Defendants Knew About, or Recklessly Disregarded, the Off-Label Promotion Scheme for Fanapt

74. At all relevant times after Vanda obtained the rights to sell Fanapt in early 2015, Defendants engaged in an off-label promotion scheme to market and sell Fanapt. Defendants conducted this scheme because Fanapt was a difficult antipsychotic to sell on-label due to its limited indication (adults with schizophrenia), its status as a second line treatment, its risk of developing a serious side effect called QT prolongation, and its requirement to be administered twice-daily, as opposed to once-a-day.

75. When Vanda began marketing and selling Fanapt in early 2015, it only had 12 sales representatives covering the drug. These 12 sales representatives were termed the "Fanapt 12" by defendant Polymeropoulos.

76. The Fanapt 12 were focused on selling Fanapt to psychiatrists in New York City and St. Louis and were overseen by one RBL.

77. Defendants decided to expand the sales force for Fanapt in November 2015 to increase the Company's footprint throughout the United States.

78. To that end, Vanda hired: Gardner; Bourgeois; two other RBLs; promoted one of the Fanapt 12 to RBL; and 39 new sales representatives in November 2015. This brought the sales team for Fanapt to 50 sales representatives and six RBLs as of November 2015. These 50 sales representatives were termed the "Fanapt 50" by defendant Polymeropoulos.

79. The six RBLs reported directly to James. According to Gardner and Bourgeois, James reported directly to the CCO (defendant Gibbs and then defendant Reverberi).

80. In addition, according to Gardner and Bourgeois, before the Class Period Vanda hired a consultant, Paul Ramirez ("Ramirez"), an attorney, to assist James with promoting and selling Fanapt. According to Gardner and Bourgeois, Ramirez served as a consultant to Vanda at least until Bourgeois left Vanda in June 2018.

81. According to Gardner and Bourgeois, Ramirez was hired directly by defendant Polymeropoulos to serve as his consultant. Gardner and Bourgeois understood that Vanda specifically structured Ramirez's role with the Company so as to not have a formal employment relationship. Nonetheless, according to Gardner and Bourgeois, Ramirez reported directly to defendant Polymeropoulos and maintained an office in the Company's Washington, D.C. headquarters.

82. The Fanapt 50, the RBLs, and Vanda senior management, including defendant Polymeropoulos, attended a five-day national Fanapt launch meeting from November 30, 2015 to December 4, 2015, at the Fairmount Hotel in Washington, D.C. (the "November 2015 Meeting").

83. According to Gardner, the following members of Vanda's senior management were in attendance at the November 2015 Meeting: (i) defendant Polymeropoulos; (ii) defendant Kelly; (iii) defendant Gibbs; (iv) defendant Reverberi; (v) James; and (vi) Ramirez.

84. According to Gardner, Vanda's senior management consisted of defendants Polymeropoulos, Kelly, Gibbs (and then Reverberi when he replaced Gibbs), and James (and then Griffin (defined below) when he replaced James). Gardner also considered Ramirez to be a member of senior management, even though Ramirez was not formally an employee of Vanda.

85. According to Gardner, Vanda's senior management conducted Fanapt sales training at the November 2015 Meeting.

86. Fanapt was a difficult drug for the Fanapt 50 to market and sell on-label. One of the main reasons is because Fanapt's competitor drugs were indicated to treat not only schizophrenia, but also other related mental illnesses such as bipolar disorder. Fanapt, however, was only approved to treat schizophrenia.

87. Nonetheless, at the November 2015 Meeting, Vanda's senior management trained its Fanapt sales force to market and sell Fanapt off-label for mental illnesses related to schizophrenia, especially bipolar disorder. According to Gardner and Bourgeois, the Fanapt 50 were trained at the November 2015 Meeting to promote and sell Fanapt regardless of the underlying condition it was being prescribed to treat.

88. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the Fanapt 50 and the RBLs that, because it was very difficult to get schizophrenia drugs approved by the FDA, doctors would understand that if Fanapt was approved to treat schizophrenia this meant Fanapt would also be effective in treating other mental health disorders, including bipolar disorder and depression.

89. According to Bourgeois, Vanda's sales force for Fanapt was trained to convince doctors that Fanapt was just as effective as other antipsychotics that treat both schizophrenia and bipolar disorder, without regard to whether Fanapt was being prescribed to treat schizophrenia, meaning on-label, or to treat bipolar disorder or another mental illness, meanings off-label.

90. According to Gardner, the Fanapt sales representatives were trained to avoid the subject of Fanapt being indicated only for schizophrenia. Gardner recounts that the sales aide for Fanapt distributed by Vanda to its sales representatives (the "Fanapt Sales Aide") specifically

directed the sales representatives to push Fanapt even if a doctor stated he or she does not have schizophrenia patients.

91. According to Gardner, who retained a copy of the Fanapt Sales Aide that is referenced in the complaints in the Qui Tam Litigation, the Fanapt Sales Aide provided the following question and answer scenario, which was the very first such example given in the "overcoming objections" section: the doctor objection is "I don't see any/a lot of patients with schizophrenia" and Vanda's preferred response is "You don't see a lot of schizophrenia but you do use atypical antipsychotics, correct?" Gardner recounts that the sales training for the Fanapt sales representatives primarily focused on this portion of the Fanapt Sales Aide.

92. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt sales representatives role-played mock sales calls for Vanda's senior management. On the occasions where the sales representative would fail to mention schizophrenia, Vanda's senior management would not correct the sales representative or instruct him or her to mention the need to discuss schizophrenia. In fact, according to Gardner and Bourgeois, they felt that avoiding the word schizophrenia was viewed as a positive by Vanda's senior management.

93. According to Gardner, the Fanapt 12 also participated in the November 2015 Meeting. Gardner recounts that the Fanapt 12 described marketing and promoting Fanapt off-label in a manner similar to the training at the November 2015 Meeting for the Fanapt 50.

94. Further, part of Gardner's job at the November 2015 Meeting was to certify that sales representatives were properly trained to sell and promote Fanapt. To that end, Gardner was responsible for meeting with and grading a Fanapt 12 sales representative from New York. During the meeting, Gardner determined that the New York sales representative was engaging in off-label promotion and Gardner refused to certify the sales representative.

95. Thereafter, Gardner recounts that James and Ramirez expressed annoyance at Gardner's decision to not certify the New York sales representative, even after Gardner explained his reasoning. According to Gardner, the New York sales representative went in for testing again at the November 2015 Meeting before James, without Gardner, and the New York sales representative was certified.

96. According to Gardner and Bourgeois, Vanda encouraged its sales representatives to market Fanapt by promoting its propensity for not causing akathisia, which is a movement disorder characterized by a feeling of inner restlessness that is a common side effect of antipsychotics. Fanapt has a relatively low incidence of akathisia compared to other antipsychotics.

97. According to Gardner and Bourgeois, Vanda improperly used Fanapt's low incidences of akathisia to promote Fanapt off-label for the treatment of non-schizophrenia mental disorders. For example, the Fanapt Sales Aide provided Vanda's preferred response to the doctor objection that "Fanapt has only one indication," as follows:

> I understand that other antipsychotics have more than one indication. Can you think of any of your adult schizophrenia patients who are experiencing inner restlessness, agitation or other treatment-induced movement disorders on their current medication?
>
> ***The Fanapt efficacy and tolerability profile, including its placebo-like rate of akathisia make it an option for patients who need to switch from one antipsychotic to another***.

98. According to Gardner and Bourgeois, the point that Vanda sought to impart on its Fanapt sales representatives was that Fanapt should be promoted as an alternative to all antipsychotics, regardless of whether the patient has schizophrenia, because Fanapt reduces the effects of akathisia.

99. To that end, according to Gardner, the Fanapt Sales Aide included the following additional preferred Vanda responses to the doctor objection that: "I don't see any/a lot of patients

with schizophrenia," as follows: "Akathisia is a drug-induced side effect that can necessitate a treatment switch" and "Fanapt offers atypical antipsychotic efficacy with placebo-like rates of Akathisia."

100. According to Gardner and Bourgeois, by shifting the focus to akathisia and away from the doctor's stated concern that Fanapt would not be appropriate for his or her patients because they do not have schizophrenia, Vanda was promoting and marketing Fanapt off-label.

101. According to Bourgeois, defendant Polymeropoulos informed him during the November 2015 Meeting that every patient with akathisia should be on Fanapt.

102. According to Gardner, Vanda's focus on akathisia at the expense of schizophrenia resulted in objections to Vanda's marketing strategy by Kate Holland ("Holland"), Vanda's Vice President of Sales and Marketing from May 2012 to January 2016.

103. According to Gardner, defendant Polymeropoulos asked Holland to alter the marketing strategy for Fanapt to make it more aggressive. According to Gardner, Holland resigned in January 2016 after refusing defendant Polymeropoulos's request.

104. Also departing Vanda around this time was defendant Gibbs, who only began working at Vanda in April 2015. According to the 12/21/15 Form 8-K, defendant Gibbs resigned after only eight months and forfeited his right to any severance or other post-termination benefits typically afforded to departing corporate executives.

105. According to the 12/21/15 Form 8-K, defendant Reverberi immediately replaced defendant Gibbs as Vanda's CCO.

106. Vanda also ensured that Fanapt would be promoted off-label based because it trained sales representatives to convince doctors to switch to Fanapt from Risperidone, Latuda and Saphris – competitor antipsychotics that are FDA-approved to treat both schizophrenia and bipolar disorder.

107. According to Gardner and Bourgeois, Vanda senior management set sales goals for the Fanapt 50 based on the total market for antipsychotics without accounting for the fact that competitor drugs treat more indications than schizophrenia. According to Gardner and Bourgeois, this resulted in the Fanapt 50 having to promote Fanapt off-label or they would be unable to meet their sales goals because Fanapt could only treat a small portion of the relevant antipsychotic market on-label.

108. According to Gardner and Bourgeois, the RBLs, defendant Reverberi, James, and Ramirez participated in a conference call in June 2016 where, among other things, defendant Reverberi confronted the RBLs for not growing Fanapt faster. Several RBLs expressed frustration at the fact that Fanapt is only approved for one indication, thereby limiting the pool of potential sales, to which defendant Reverberi responded "doctors can use Fanapt anywhere they want." Defendant Reverberi warned the RBLs on the call that their failure to increase Fanapt sales would jeopardize their jobs. After the conference call, Gardner and Bourgeois discussed whether they had just been threatened by defendant Reverberi.

109. According to Bourgeois, he participated in a call with defendant Reverberi in June 2018 to discuss the Fanapt 50's inability to grow Fanapt prescriptions at the rate desired by Vanda's senior management. During this meeting, Bourgeois explained to defendant Reverberi that doctors were reporting that they were having extreme difficulties getting Fanapt approved by insurers because it was being prescribed off-label. In response, defendant Reverberi told Bourgeois that he did not believe Bourgeois, and asked Bourgeois what his plan was to turn around Fanapt sales.

110. According to Bourgeois, on one occasion in early 2018, Kate Arnold ("Arnold"), Vanda's Head of Compliance from February 2017 to the present, contacted Bourgeois after reviewing his sales representative reports because Bourgeois had written that sales representatives

need to "push" doctors to prescribe Fanapt. Bourgeois included this language in his sales representative reports because that is what he was instructed to do by Tom Griffin ("Griffin"), Vanda's Vice President of Sales from 2017 to the present.

111. According to Bourgeois, Griffin was the permanent replacement for James, who departed from Vanda in July 2016. Bourgeois recounts that, like James, Griffin reported directly to defendant Reverberi during the Class Period.

112. According to Bourgeois, Arnold asked him to change this language because defendant Polymeropoulos was concerned about being sued by the government. Arnold further stated that Bourgeois was not the only RBL with this issue, and that she had spoken to other RBLs about changing similar language regarding pushing doctors to prescribe Fanapt.

113. According to Bourgeois, during early 2018, defendant Reverberi would inquire about how Bourgeois could get more Fanapt prescriptions from Dr. Boris Rubashkin ("Rubashkin"), a psychiatrist in Houston, Texas. Rubashkin was a large prescriber of Fanapt. Brandy Barrington ("Barrington"), who was employed at Vanda from January 2016 to September 2018, was the Vanda sales representative responsible for interacting with Rubashkin. Bourgeois informed defendant Reverberi that Rubashkin had informed Barrington that he was already using Fanapt in every schizophrenia patient he had in his practice. Nonetheless, defendant Reverberi pushed Bourgeois to find a way to increase Fanapt prescriptions from Rubashkin, even though Bourgeois made it clear that there were no additional schizophrenia patients to add from Rubashkin's practice.

114. Vanda's intent to promote Fanapt off-label is also illustrated by how it compensated the Fanapt 50, which was to pay them on, to use Vanda's terminology, "total dirt." This meant that Vanda paid its sales representatives for every Fanapt prescription written in their territory, regardless of the condition it was written to treat, meaning both on-label and off-label sales.

115. On several occasions during his employment with Vanda, Gardner stated to Vanda senior management that incentive compensation should not be based on total dirt and, instead, should only be based on approved call targets only, meaning doctors treating adult schizophrenia patients.

116. Gardner made this recommendation because he was concerned that paying sales representatives on total dirt incentivized off-label promotion. In fact, Gardner stated to Ramirez in on one occasion that "Vanda is paying for off-label promotion" and "the sales goals are based on illegitimately earned prescriptions." In response, Ramirez warned Gardner not to use the word "illegitimate" again and told Gardner not to bring up the off-label topic again and not to send Ramirez any emails about paying on total dirt.

117. According to Bourgeois, in a meeting with Griffin and the RBLs in April 2018, the RBLs expressed concern about paying Fanapt sales representatives on total dirt. During this discussion, Griffin stated that the decision to pay on total dirt was made by senior management, and it was not changing.

118. Defendants further knew, or recklessly disregarded, that Fanapt was being promoted off-label because, according to Gardner and Bourgeois, Vanda's senior management had access to information apprising them of the precise volume and percentage of Fanapt sales that were made off-label. According to Gardner, early in his employment at Vanda he was informed by senior management that the Company received ICD-9 data for each prescription for Fanapt.[3] This ICD-9 data consisted of the indication each Fanapt prescription was written for (the ICD-9 diagnosis code) and the dosage amount (the NDC code). According to Bourgeois, Vanda's senior management

[3] ICD-9 is a list of codes corresponding to diagnoses and procedures that are entered into a patient's electronic health record and are used for diagnostic, billing, and reporting purposes.

would know exactly how many Fanapt prescriptions were being written off-label by viewing the ICD-9 data that the Company routinely received.

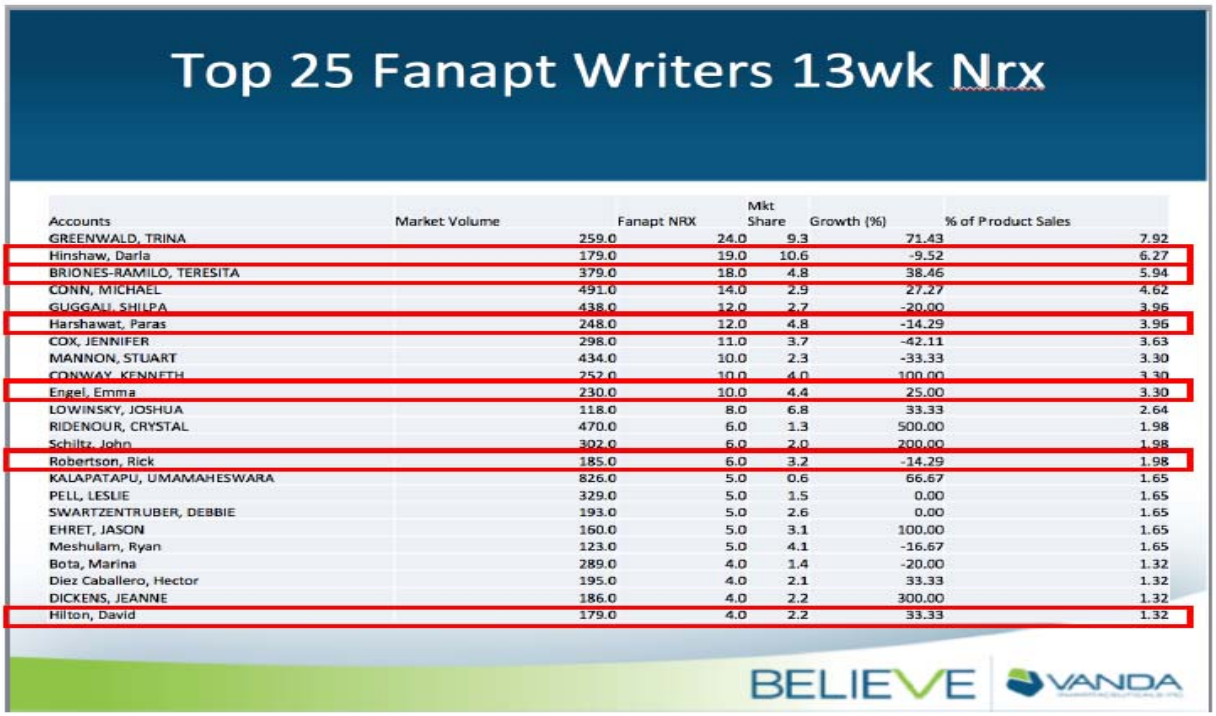
119. In addition, Vanda's senior management was informed by at least one Fanapt sales representative that Fanapt prescriptions were being written off-label during the Class Period. According to Gardner, in March 2016, Dallas Medenwald ("Medenwald"), a member of the Fanapt 50 who covered the state of Indiana, called Gardner because the Indiana Medicaid program was changing its coverage to no longer reimburse for off-label antipsychotics, resulting in a loss of 400 prescriptions per month in Indiana. Gardner informed James and Ramirez that 400 prescriptions had been lost in Indiana and that they all were off-label prescriptions.

120. Vanda also engaged in off-label promotion of Fanapt during the Class Period by targeting children with schizophrenia, instead of the adults that Fanapt was approved by the FDA to treat. According to Gardner, the 400 prescriptions lost by Medenwald in Indiana all came from child psychiatrists who were prescribing Fanapt off-label to pediatric patients. Gardner confirmed that James and Ramirez were told that the reason why the 400 lost prescriptions in Indiana were off-label was because they were prescribed to pediatric patients.

121. According to Gardner and Bourgeois, Vanda senior management required each of the Fanapt 50 to target the top 25 prescribers of all antipsychotics in their territory, with the instruction to focus their sales efforts on convincing these doctors to prescribe Fanapt.

122. According to Gardner and Bourgeois, these top 25 prescribers were placed in charts by the Company. According to Gardner and Bourgeois, these top 25 prescriber charts often included child psychiatrists who, by definition, cannot prescribe Fanapt on-label because they do not treat adults.

123. For example, in the complaints in the Qui Tam Litigation, Gardner provided the following top 25 chart for Vanda's Indiana territory, with the child psychiatrists highlighted:



Accounts	Market Volume	Fanapt NRX	Mkt Share	Growth (%)	% of Product Sales
GREENWALD, TRINA	259.0	24.0	9.3	71.43	7.92
Hinshaw, Darla	179.0	19.0	10.6	-9.52	6.27
BRIONES-RAMILO, TERESITA	379.0	18.0	4.8	38.46	5.94
CONN, MICHAEL	491.0	14.0	2.9	27.27	4.62
GUGGALI, SHILPA	438.0	12.0	2.7	-20.00	3.96
Harshawat, Paras	248.0	12.0	4.8	-14.29	3.96
COX, JENNIFER	298.0	11.0	3.7	-42.11	3.63
MANNON, STUART	434.0	10.0	2.3	-33.33	3.30
CONWAY, KENNETH	252.0	10.0	4.0	100.00	3.30
Engel, Emma	230.0	10.0	4.4	25.00	3.30
LOWINSKY, JOSHUA	118.0	8.0	6.8	33.33	2.64
RIDENOUR, CRYSTAL	470.0	6.0	1.3	500.00	1.98
Schiltz, John	302.0	6.0	2.0	200.00	1.98
Robertson, Rick	185.0	6.0	3.2	-14.29	1.98
KALAPATAPU, UMAMAHESWARA	826.0	5.0	0.6	66.67	1.65
PELL, LESLIE	329.0	5.0	1.5	0.00	1.65
SWARTZENTRUBER, DEBBIE	193.0	5.0	2.6	0.00	1.65
EHRET, JASON	160.0	5.0	3.1	100.00	1.65
Meshulam, Ryan	123.0	5.0	4.1	-16.67	1.65
Bota, Marina	289.0	4.0	1.4	-20.00	1.32
Diez Caballero, Hector	195.0	4.0	2.1	33.33	1.32
DICKENS, JEANNE	186.0	4.0	2.2	300.00	1.32
Hilton, David	179.0	4.0	2.2	33.33	1.32

124. In addition, Vanda had a competition for the Fanapt 50 called "10 to win," which paid an additional bonus every four to six weeks to the sales representative who had the most new prescription growth from a list of ten physicians in their territory chosen by the sales representatives. According to Gardner and Bourgeois, the "10 to win" lists contained child psychiatrists who, by definition, cannot prescribe Fanapt on-label because they do not treat adults.

125. For example, in the complaints in the Qui Tam Litigation, Gardner provided the following "10 to win" chart for Vanda's Indiana territory, with the child psychiatrists highlighted:

126. By allowing child psychiatrists to be included in the Company's target lists, Gardner and Bourgeois understood that Defendants intended for Vanda's sales representatives to promote Fanapt off-label.

127. According to Gardner, who retained copies of the top 25 and "10 to win" charts that are referenced in the complaints in the Qui Tam Litigation, these charts were available to everyone in Vanda's senior management and went right up to defendant Polymeropoulos.

128. Another type of off-label promotion that Vanda engaged in for Fanapt during the Class Period involved promoting the drug as a first line treatment even though Fanapt was only approved by the FDA as a second line treatment.

129. According to Gardner and Bourgeois, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs that if Fanapt were approved in November 2015 that it would be

approved as a first line drug. For this reason, the Fanapt 50 received no training on ensuring that the patients being prescribed Fanapt had tried another antipsychotic first. In fact, according to Gardner, defendant Polymeropoulos stated at the November 2015 Meeting that most patients will have tried other drugs before being prescribed Fanapt, meaning sales representative did not need to inquire about it.

130. According to Bourgeois, the fact that Fanapt was a second line treatment was not included in any of the promotional materials provided to Fanapt's sales representatives.

131. Even worse, according to Bourgeois, during a 2017 conference call, Ramirez stated to Fanapt's sales representatives that Fanapt was a "first in class" drug. Bourgeois recounts being confused and concerned by this statement because Fanapt's FDA label clearly describes the drug as a second line treatment.

132. Notwithstanding the seriousness of QT prolongation as a side effect and Fanapt's black box warning, according to Gardner, the Fanapt Sales Aide instructed sales representatives to downplay this risk, stating, in pertinent part, as follows:

> ***if Fanapt was approved today, it would not have received the QTc Interval Prolongation warning***. When the FDA approved Fanapt years ago, there was very little data about QTc Interval Prolongation so it was blown out of proportion. ***Now, it is no longer a concern and if Fanapt were approved today it would not have the QTc Prolongation side effect warning***.

133. According to Gardner, at the November 2015 Meeting, sales representatives were trained by defendant Polymeropoulos to tell doctors that Latuda and Saphris do not have QT prolongation warnings because those drugs were approved years after Fanapt and the FDA no longer considers QT prolongation a serious issue.

134. Gardner's contemporaneous notes from a manager meeting he participated in while employed at Vanda confirm that Vanda was training its sales representatives to downplay, or not

even mention, the risk of developing QT prolongation posed by Fanapt. As stated in the complaints in the Qui Tam Litigation, these notes stated, in pertinent part, that:

> Any A-Typical launched post Latuda will no longer have QT Prolongation as part of the [package insert] as [the] ***FDA realizes [QT Prolongation] is no long worth noting***. [The number of patients experiencing QT Prolongation] are too small to be an issue.

135. According to Bourgeois, Vanda did not address QT prolongation with Fanapt's sales representatives other than defendant Polymeropoulos mentioning at the November 2015 Meeting that it was no longer a relevant concern.

136. According to Gardner and Bourgeois, by not taking steps to properly train Fanapt's sales representatives on the risk of QT prolongation, and the related designation of Fanapt as a second line treatment, Vanda was promoting Fanapt off-label because sales representatives were promoting it as a first line treatment.

137. Vanda also engaged in off-label promotion of Fanapt during the Class Period by training its sales representatives to market Fanapt as being a once-daily drug, even though Fanapt's FDA label required Fanapt to be taken twice a day.

138. Fanapt's twice daily usage put it at a disadvantage compared to other antipsychotic medications, such as Risperidone and Latuda, which are once-daily formulations. According to Gardner, doctors prefer once-daily antipsychotics because patients with a mental illness are less likely to stay compliant with a medication schedule that requires multiple doses each day.

139. According to Gardner, during the November 2015 Meeting, defendant Polymeropoulos told the RBLs and the Fanapt 50 that Fanapt should have been approved for a once-daily dosing and "many people have told me that I should go back to the FDA and request approval for QD [once a day] dosing for Fanapt because Fanapt's half-life of 23 1/2 hours is so long."

140. According to Gardner, based on this comment, Vanda's sales representatives were trained to promote Fanapt by stating that its 23 1/2 hour half-life meant that Fanapt could be prescribed once-daily, notwithstanding the FDA label. In fact, during the November 2015 Meeting, Gardner recalled defendant Polymeropoulos stating that "[d]octors will ask you if Fanapt can be dosed once daily because of the long half-life and you know what the answer to that question is? It can be!"

141. According to Gardner, in the overcoming objections portion of the Fanapt Sales Aide, Vanda provided the following guidance if a doctor stated that Fanapt's "dosing is not practical for schizophrenia patients," as follows: "Fanapt half-life is 18-26 hours." According to Gardner, sales representative understood this to mean that Fanapt should be promoted as a once-daily drug, notwithstanding Fanapt's FDA label.

142. Taken collectively, the above allegations demonstrate that Vanda engaged in a multifaceted off-label promotion scheme for Fanapt during the Class Period, including: (i) marketing Fanapt to treat mental disorders other than schizophrenia; (ii) focusing on akathisia to distract doctors from the underlying condition Fanapt was being used to treat; (iii) providing unrealistic sales targets that required off-label promotion in order to be met; (iv) compensating sales representatives for off-label sales; (v) targeting pediatric patients as part of the sales efforts for Fanapt; (vi) presenting Fanapt as a first line treatment; (vii) downplaying the extent and severity of QT prolongation; and (viii) promoting that Fanapt can be administered once-daily.

143. Vanda's long-running off-label promotion scheme for Fanapt rendered false and misleading the repeated statements made by Defendants during the Class Period regarding the Fanapt 50, how Fanapt was being promoted and sold, and other representations in Vanda's SEC filings regarding Fanapt's marketing. By repeatedly speaking about the topic of Vanda's marketing

and promotional efforts for Fanapt, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose the off-label promotion scheme for Fanapt, these statements omitted material information from Vanda's investors, thereby rendering Defendants' Class Period statements materially false and misleading.

The FDA Approves Hetlioz Shortly Before the Class Period

144. On May 31, 2013, Vanda submitted an NDA to the FDA "to support marketing of tasimelteon, a melatonin agonist, for the treatment of Non-24 hour sleep-wake disorder (Non-24) in totally blind patients."

145. According to the FDA's Summary Review of the Hetlioz NDA, Non-24 occurs principally, if not totally, in blind individuals. Specifically, the FDA's Summary Review states, in pertinent part, that:

> Non-24 hour sleep-wake disorder is characterized by a mismatch between the timing of the sleep-wake cycle and the 24-hour day because of a lack of environmental light input ***in completely blind individuals***. As the individual "biological clock" runs longer than 24 hours in most people, the absence of light input creates a cyclical misalignment of sleep and wakefulness with the 24-hour day.

146. According to the National Sleep Foundation ("NSF"), which is nonprofit foundation whose largest single source of funding is pharmaceutical companies, Non-24 requires a formal diagnosis by a doctor.

147. In particular, according to the NSF, "blood, saliva, or urine should be collected [by a doctor] over several weeks to look for circadian biochemical chemical rhythms that can determine for sure whether the clock is exhibiting a non-24-hour rhythm." This is because Non-24 "has been misdiagnosed for other sleep deprivation or non-related psychiatric disorders in the past." Thus, according to the NSF, Non-24 should be tested for and observed by medical professionals before an individual is determined to have Non-24, as opposed to a different kind of sleep disorder.

148. Non-24 rarely, if ever, occurs in sighted individuals. According to Robert Sack, M.D., of the Oregon Health and Sciences University, who MedPage Today stated on March 28, 2014, is an expert on Non-24, "there have been fewer than 100 cases of sighted people with Non-24 sleep-wake disorder reported in the scientific literature."

149. Before the Class Period, Defendants repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals. For example, in an investor presentation that Vanda filed on Form 8-K on March 9, 2010, the Company described Non-24 as a disorder that "***[o]ccurs almost entirely in subjects who are totally blind*** and lack the light sensitivity necessary to reset the circadian clock."

150. In support of the NDA for Hetlioz, Vanda conducted two clinical trials involving Hetlioz. According to the FDA label for Hetlioz, both studies involved "totally blind patients with Non-24."

151. In a January 26, 2012, press release issued by Vanda, which was also issued on Form 8-K that same day, announcing initial trial results from one of the clinical trial referenced in the FDA label for Hetlioz, Vanda stated, in pertinent part, as follows:

> ***Tasimelteon is a circadian regulator in development for the treatment of Non-24-Hour Disorder in totally blind individuals with no light perception***.
>
> * * *
>
> Circadian regulation is necessary for the treatment of Non-24-Hour Disorder and it is predictive of a beneficial effect on both nighttime sleep and daytime naps. While light resets the body clock in sighted individuals, keeping it synchronized with the 24-hour day, this effect is lost in totally blind individuals with no light perception.

152. On November 14, 2013, Vanda issued a press release, which was subsequently filed on Form 8-K on November 15, 2013 (the "11/15/13 Form 8-K"), announcing that the FDA had voted to recommend the approval of Hetlioz "for the treatment of Non-24-Hour Disorder (Non-24) in the totally blind."

153. In commenting on this development, defendant Polymeropoulos stated in the 11/15/13 Form 8-K, in pertinent part, that: "[w]e are now one step closer toward our goal of providing a treatment option that addresses the physiologic cause of this serious, debilitating orphan condition that impacts a majority of totally blind individuals."

154. Hetlioz became officially approved by the FDA in January 2014.

155. Notwithstanding that the NDA for Hetlioz acknowledged that it was to treat Non-24 in blind individuals, on January 31, 2014, the FDA sent Vanda a letter clarifying that Hetlioz had been approved for sale in the United States to treat Non-24 regardless of whether or not the patient was blind.

156. During the Class Period, Defendants continued to acknowledge that Non-24 rarely, if ever, occurs in sighted individuals, even as the Company aggressively marketed and promoted Hetlioz off-label to sighted individuals, as discussed herein.

157. For example, on March 7, 2017, defendant Kelly participated at the Cowen Health Care Conference and stated to Vanda's investors, in pertinent part, as follows:

> But first, some background on non-24 itself. This is a rare circadian rhythm disorder that impacts approximately 80,000 individuals in the US. ***It occurs almost exclusively in the totally blind***, and these are blind individuals without light perception which, in turn, inhibits their ability to reset their circadian clock.

158. Once Hetlioz received FDA approval, Vanda rapidly increased its price. According to STAT, Vanda sold Hetlioz for approximately $79,600 per year at the time of its approval in 2014.

159. STAT further reported that, by May 2016, Vanda had substantially increased the price of Hetlioz, increasing it by approximately 76% to $148,000 per year.

160. Vanda has continued to substantially increase the price of Hetlioz. According to GoodRX, the average monthly price of Hetlioz as of February 2019 was $18,600, equaling a yearly

price of $223,200, a 50.8% increase since May 2016 and a staggering 180.4% increase since Hetlioz received FDA approval in January 2014.

Defendants Knew About, or Recklessly Disregarded, the Off-Label Promotion Scheme for Hetlioz

161. Although Vanda repeatedly acknowledged that Non-24 rarely, if ever, occurs in sighted individuals, the Company focused its promotional efforts for Hetlioz during the Class Period in sighted individuals regardless of whether they had Non-24.

162. Even worse, Vanda's promotional efforts for Hetlioz were concentrated on psychiatrists, who focus on the diagnosis and treatment of mental health disorders, not blind patients, let alone patients who may be experiencing any type of sleeping disorder, least of all Non-24. Instead, Defendants undertook a scheme to promote Hetlioz off-label during the Class Period, which was never disclosed to investors.

163. According to Gardner and Bourgeois, during the November 2015 Meeting, the Fanapt 50 and the RBLs were instructed to ensure that Hetlioz was introduced to the psychiatrists that were being targeted for Fanapt.

164. According to Gardner, to pitch Hetlioz to psychiatrists, defendant Polymeropoulos instructed the RBLs to direct the sales representatives to ask the doctors "do you have any blind patients?" Regardless of the answer, the sales representatives were instructed to state that "Hetlioz is a drug that is effective in treating circadian rhythm disruption" and to leave the doctor with a Hetlioz sales packet.

165. Defendant Polymeropoulos told the RBLs that psychiatrists would understand that if Hetlioz treats circadian rhythm disruption in Non-24 that it could also treat non-blind patients with other sleep disorders caused by circadian rhythm disruption, such as shift work sleep disorder, jet lag, and insomnia.

166. According to Gardner and Bourgeois, this sales pitch was designed to, and in fact did, result in off-label prescriptions of Hetlioz.

167. According to Gardner and Bourgeois, at no point in time during either of their employments with Vanda did anyone discuss with them that a doctor can diagnose Non-24 or that blood and urine tests can be used to assist in a Non-24 diagnosis. To the contrary, Gardner and Bourgeois recount that Vanda informed them that there was no way to tell if someone had Non-24, which is why the drug could be used to treat any circadian rhythm disorder.

168. According to Bourgeois, if physicians would inquire about whether there was any way to test patients for Non-24, Vanda trained its representatives to respond by pivoting the conversation to discussing that individuals with mental disorders were good candidates for Hetlioz because many of them have difficulty sleeping.

169. After the Fanapt 50 pitched Hetlioz to a psychiatrist, they were required to pass the account over to a Hetlioz sales representative, who would try to close the sale. Vanda referred to these as "pass-alongs." Vanda informed the Fanapt 50 that they would be held accountable for how many pass-alongs they provided to the Hetlioz sales team. According to Gardner, the number of pass-alongs a sales representative secured was documented in these representatives' company-issued laptops following every sales call.

170. According to Gardner, in May 2016, Ramirez held a meeting with the RBLs and reprimanded them because the Fanapt 50 were not producing enough pass-alongs. During the call, some of the RBLs stated that the psychiatrists that the Fanapt 50 were contacting did not have any blind patients. Ramirez responded that it was mandatory that the Fanapt 50 promote Hetlioz on every sales call.

171. According to Bourgeois, Vanda intended to promote Hetlioz off-label for conditions other than Non-24. Bourgeois recounts that sales representatives were trained to respond to a question from doctors asking if Hetlioz is only for blind patients by stating that if a patient does not have normal sleep habits, then they should use Hetlioz regardless of whether they are blind.

172. According to Bourgeois, some doctors would ask how they could tell if their patients had Non-24. Bourgeois recounts that Vanda trained its sales representatives to respond by telling the doctor that if their patient had tried other sleep aides and were still experiencing sleep issues, that they probably have Non-24.

173. According to Bourgeois, several sales representatives expressed concerns about selling Hetlioz to sighted patients and asked Vanda's senior management to see data that supported the efficacy of Hetlioz in sighted patients. Bourgeois recounts that Vanda's senior management responded that Non-24 occurs in blind patients but also those with mental conditions, so if a psychiatrist has patients who have trouble sleeping, and have tried Ambien and it did not work, that they should prescribe Hetlioz.

174. According to Bourgeois, Vanda's promotional materials for Hetlioz also demonstrated an intent to promote Hetlioz off-label because they did not focus on patients with Non-24. Instead, the call guidance sheets for Hetlioz instructed sales representatives to tell doctors that "Non-24 has been associated with traumatic brain injury and depressive and bipolar mood disorders. Blindness is also a risk factor."

175. In addition, according to Bourgeois, in early 2018 he was contacted by Arnold regarding his usage of the word "sleep" as opposed to "Non-24" in his sales representative reports for Hetlioz. Bourgeois recounts that Arnold told him that the word "sleep" needed to be removed from Hetlioz sales representative reports because defendant Polymeropoulos was concerned about

being sued by the government. Bourgeois ultimately removed "sleep" from his Hetlioz sales representative reports.

176. According to Bourgeois, Arnold informed him that other RBLs were using the word "sleep" in their Hetlioz sales representative reports and that she had been raising the same concerns with them.

177. Further, according to Bourgeois, Hetlioz was being promoted off-label because certain sales representatives were able to obtain an out-sized number of prescriptions written for Hetlioz, while most struggled to achieve more than one or two prescriptions per fiscal quarter.

178. Bourgeois recounts that Scott Grontkowski ("Grontkowski"), a Vanda sales representative from Rockford, Illinois, from January 2017 to the present, had gotten doctors to write over 50 prescriptions for Hetlioz in a quarter. According to Bourgeois, none of these prescriptions were for blind patients.

179. In FY17, Vanda sold $89.978 million worth of Hetlioz. At Hetlioz's May 2016 price of $148,000 per year (a price that had undoubtedly risen by 2017), this meant that Vanda had written approximately 608 prescriptions for Hetlioz during FY17. Assuming he only sold 50 prescriptions, Grontkowski accounted for approximately 8.2% of the Hetlioz prescriptions written in FY17.

180. According to Bourgeois, Grontkowski was asked by Vanda to present at the Company's 2018 national sales meeting (the "2018 Meeting") to demonstrate his pitch for selling Hetlioz. The 2018 Meeting, which took place in Washington, D.C., was attended by Griffin, Ramirez, and defendant Reverberi.

181. Bourgeois recounts that Grontkowski's sales pitch during the 2018 Meeting contained nothing about Hetlioz's efficacy in treating Non-24. Instead, Bourgeois recounts that Grontkowski

stated during the 2018 Meeting that Grontkowski tells doctors if they have patients who cannot sleep, they should prescribe them Hetlioz to get them sleeping right now.

182. During the early part of the Class Period, Defendants did not acknowledge that its Fanapt sales force was being used to promote Hetlioz to psychiatrists. That changed in July 2017, when Vanda announced it was beginning the "Hetlioz to Psychiatrists Initiative," which Defendants termed "HPI." According to Defendants, the HPI involved having Fanapt sales representatives call psychiatrists to promote Hetlioz.

183. According to Gardner and Bourgeois, however, even though the HPI was announced as beginning in July 2017, Vanda had been using Fanapt sales representatives to promote Hetlioz for years before the announcement, since at least November 2015.

184. As stated in the Aurelius Report (defined below), which was based, in part, on interviews with unnamed former Vanda employees and an unnamed sleep doctor, according to a former unnamed Vanda sales representative "[w]e were [internally] saying 'give it to everyone who doesn't sleep well.'" The unnamed sleep doctor in the Aurelius Report opined that "[Vanda is] prescribing [Hetlioz] off label and calling it's [sic] something it's not." The Aurelius Report further demonstrates that Vanda was engaged in an off-label promotion scheme for Hetlioz during the Class Period.

185. The Aurelius Report was issued during the trading day on the last day of the Class Period, February 11, 2019. The Aurelius Report publicly revealed for the first time, among other things, Defendants' off-label marketing scheme for both Fanapt and Hetlioz. On this news, the trading price of Vanda's common stock declined $1.05 per share, or 5.51%.

186. Vanda's long-running off-label promotion scheme for Hetlioz rendered false and misleading the repeated statements made by Defendants during the Class Period regarding how

Hetlioz was being promoted and sold, and other representations in Vanda's SEC filings regarding Hetlioz's marketing. By repeatedly speaking about the topic of Vanda's marketing and promotional efforts for Hetlioz, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose the off-label promotion scheme for Hetlioz, these statements omitted material information from Vanda's investors, thereby rendering Defendants' Class Period statements materially false and misleading.

Tradipitant Was Vanda's Most Important Clinical Pipeline Drug During the Class Period

187. Of the three or four drugs that Vanda had in clinical development during the Class Period, tradipitant was the most promising in terms of potentially obtaining FDA approval so that the Company could market and sell the drug.

188. Indeed, according to defendant Polymeropoulos during the 11/7/18 Call (defined below), "[t]radipitant [is] the most exciting clinical milestone for Vanda[.]" For this reason, investors and analysts were highly focused on tradipitant's prospects during the Class Period.

189. Tradipitant was being clinically tested by Vanda during the Class Period for two potential indications: (i) gastroparesis, a disorder that prevents the stomach from emptying of food in a normal fashion; and (ii) atopic dermatitis, or eczema.

190. According to defendant Polymeropoulos, tradipitant's potential for treating gastroparesis presented a significant economic opportunity for Vanda. During the 12/3/18 Conference Call (defined below), defendant Polymeropoulos stated, in pertinent part, that:

> Before going into more detail on the study results, I would like to provide an overview of the significant unmet medical need for gastroparesis patients.
>
> Gastroparesis is a serious chronic medical condition, characterized by delayed gastric emptying and associated with the symptoms of nausea, vomiting, bloating, fullness after meals, abdominal pain, along with significant impairment of social and occupational functioning.

> The estimated prevalence of gastroparesis in the U.S. is over 5 million people, many of whom remain undiagnosed.
>
> Gastroparesis affects mostly women, and it can be of various etiologies including diabetes mellitus and idiopathic causes.
>
> The only U.S. Food and Drug Administration approved treatment for gastroparesis is metoclopramide, approved in 1979, which due to its potential of severe side effects, carries a black box warning and has limitations of use of no more than 3 months.
>
> Patients are faced with limited therapeutic options and clinical guidelines recommend in addition to metoclopramide, the off-label use of different drugs including erythromycin, domperidone, which is not approved in the U.S., botulinum toxin injections, gastric simulators and a variety of surgical procedures in an effort to relieve, even temporarily, some of the symptoms of the disease.
>
> Gastroparesis treatment represents a significant unmet medical need as underscored by the testimonies of interested parties and advocacy organizations included the International Foundation for Gastrointestinal Disorders and Gastroparesis Patient Association for Cures and Treatments.

191. Tradipitant's potential for treating gastroparesis was a central focus of Vanda's Class Period clinical trial efforts for tradipitant.

192. Given the importance of tradipitant to Vanda's clinical pipeline, the Company spent the bulk of its direct project costs for its clinical trial drugs on tradipitant as compared to trichostatin A, AQW051, and CFTR.

193. According to the 2017 Form 10-K (defined below), Vanda spent $11.645 million on direct project costs for tradipitant during FY17 out of $15.997 million spent on direct project costs for its clinical trial drugs, or 72.7% on tradipitant.

194. According to the 1Q18 Form 10-Q (defined below), Vanda spent $2.277 million on direct project costs for tradipitant during 1Q18 out of $3.619 million spent on direct project costs for its clinical trial drugs, or 62.9% on tradipitant.

195. According to the 2Q18 Form 10-Q (defined below), Vanda spent $4.372 million on direct project costs for tradipitant during 2Q18 out of $5.974 million spent on direct project costs for its clinical trial drugs, or 73.2% on tradipitant.

196. According to the 3Q18 Form 10-Q, Vanda spent $5.113 million on direct project costs for tradipitant during 3Q18 out of $7.142 million spent on direct project costs for its clinical trial drugs, or 71.6% on tradipitant.

197. Accordingly, during the Class Period, Vanda's clinical trial efforts for tradipitant were a principal concern of investors.

Vanda Admits in the FDA Litigation Its Knowledge, or Reckless Disregard, by May 2018 that a Clinical Trial Hold Would Be Placed on Critical Tradipitant Studies

198. On May 29, 2019, Vanda filed an amended complaint in the FDA Litigation (the "Vanda FDA Complaint"). The Vanda FDA Complaint was signed by Vanda's attorneys at Mayer Brown LLP. The Vanda FDA Complaint contains Vanda's allegations against the FDA regarding a clinical trial hold that has been placed on certain tradipitant studies that were highly material and important to Vanda's investors.

199. On July 10, 2019, Vanda filed a memorandum of law in support of its motion for summary judgment in the FDA Litigation (the "Vanda SJ Brief"). The Vanda SJ Brief was signed by Vanda's attorneys at McDermott Will & Emery LLP. The Vanda SJ Brief contains citations to documents included in the Index of Administrative Records prepared by the FDA for the FDA Litigation.

200. According to the Vanda FDA Complaint, Vanda submitted its original protocol for VLY686-2301 ("Study 2301") to the FDA on August 17, 2016. Study 2301 was "a multicenter, randomized, double-blind placebo-controlled study of tradipitant for subjects diagnosed with gastroparesis."

201. According to the Vanda FDA Complaint, Study 2301 was initiated on November 22, 2016.

202. Study 2301 was a Phase II trial. According to the FDA, clinical trials are often conducted in three phases, with Phase III trials generally involving more patients and a longer duration than Phase II trials. This means that even if Study 2301 were successful, Vanda still needed to conduct a Phase III trial on gastroparesis for the FDA to approve tradipitant to treat gastroparesis.

203. According to the Vanda FDA Complaint, Vanda subsequently submitted several protocol amendments to the FDA with respect to the duration of Study 2301.

204. According to the Vanda FDA Complaint, on December 5, 2017, Vanda submitted protocol amendment #5, which, among other things, provided for Study 2301 to last for eight weeks, consisting of a four-week screening phase followed by a four-week evaluation phase.

205. According to the Vanda FDA Complaint, on April 10, 2018, Vanda submitted protocol amendment #6 to, among other things, extend Study 2301 to add a 52-week, open-label extension period. Effectively, protocol amendment #6 sought to greatly expand the duration of Study 2301.

206. According to the Vanda FDA Complaint, during a May 15, 2018, teleconference between the FDA and Vanda (the "5/15/18 Call"), the FDA informed Vanda that the Company could not extend Study 2301 to be a full year clinical trial unless Vanda completed a 9-month non-rodent toxicity study on tradipitant.

207. The FDA requires toxicity studies for drugs like tradipitant to ensure that the drug is safe for use in humans. Thus, it was unremarkable that the FDA would want tradipitant to be tested in animals for nine months before being used on humans in a one year study.

208. According to the FDA, one of their roles during the clinical trial process is to protect volunteers who participate in such trials from unreasonable and significant risk. For this reason, the FDA has the power to place a clinical hold on a trial that exposes its participants to, among other things, unreasonable or significant risk.

209. According to the FDA, "[a] clinical hold is rare; instead, FDA often provides comments intended to improve the quality of a clinical trial." This is consistent with the FDA's mandate to allow "wide latitude in clinical trial design."

210. According to the Vanda SJ Brief, at all relevant times, the FDA "made clear that continued human trials beyond 3 months [for tradipitant] would not be allowed to proceed without a 9-month [toxicity] study[.]"

211. According to the Vanda FDA Complaint, during the 5/15/18 Call, the FDA informed Vanda that, if the nine-month non-rodent study was not conducted, the FDA would place a clinical hold on Study 2301 to prevent the 52-week extension study. According to the Vanda SJ Brief, the FDA stated during the 5/15/18 Call that "'chronic toxicology studies in 2 species is a requirement, not a recommendation, prior to proceeding to long-term studies in humans.'"

212. Thus, as of the 5/15/18 Call, Defendants were fully aware that, if they chose not to conduct the nine-month non-rodent study, a fully year clinical trial for tradipitant would not be approved by the FDA.

213. According to the Vanda SJ Brief, on May 18, 2018, the FDA concluded that "'a chronic toxicology study of 9 months duration will be needed'" and that tradipitant "trials beyond 3 months 'should be put on clinical hold until the chronic toxicity study in a non-rodent species is submitted for our review.'"

214. According to the Vanda FDA Complaint, to avoid a clinical hold being placed on Study 2301, Vanda submitted an amended protocol to the FDA on May 22, 2018, that, among other things, limited Study 2301 to no more than three months in duration.

215. According to the Vanda FDA Complaint, on May 24, 2018, the FDA approved the amended protocol and allowed Study 2301 to proceed for no longer than three months in duration without having to conduct the nine-month non-rodent toxicity study.

216. According to the Vanda SJ Brief, on August 1, 2018, Vanda filed a formal dispute resolution request contesting the FDA's determination that the nine-month non-rodent toxicity study was necessary in order to conduct a clinical trial for gastroparesis in excess of three months. According to the Vanda SJ Brief, the FDA responded to this request by sending Vanda a one-page letter stating that Vanda's formal dispute "was 'not accepted.'"

217. According to the Vanda FDA Complaint, on September 26, 2018, Vanda submitted a new clinical study protocol, Study 2302, to the FDA that was the same 52-week open-label extension study that Vanda proposed as protocol amendment #6 for Study 2301.

218. According to the Vanda FDA Complaint, as of November 2018, Vanda had not begun Study 2302.

219. On December 3, 2018, the Company issued a press release, which was also filed on Form 8-K, that announced positive results from Study 2301 (the "12/3/18 Form 8-K"). According to the 12/3/18 Form 8-K, and the conference call the Company held that same day to tout the results from Study 2301, this Phase II study was successful but an additional, longer study that also had positive results was ultimately needed in order to obtain FDA approval for tradipitant to treat gastroparesis.

220. According to the Vanda FDA Complaint, on December 11, 2018, Vanda submitted a protocol amendment to Study 2301 that once again requested to add a 12-month open-label extension to Study 2301. According to the Vanda FDA Complaint, this proposed amendment to Study 2301 is similar to Study 2302.

221. According to the Vanda FDA Complaint, on December 19, 2018, the FDA informed Vanda by telephone that Study 2301 and 2302 had been placed on partial clinical holds because Vanda had not complied with the FDA's request – communicated to Vanda on the 5/15/18 Call – that the Company conduct a nine-month non-rodent toxicity to study to ensure that tradipitant is safe for long-term use in humans.

222. According to the Vanda FDA Complaint, on December 21, 2018, the FDA provided Vanda with a letter that contained a written explanation for the partial clinical trial holds placed on Study 2301 and Study 2302. According to the Vanda FDA Complaint, the FDA reiterated in its December 21, 2018 letter, in pertinent part, that "non-rodent toxicity studies of 9 months duration are required for the conduct of [Vanda's] proposed clinical investigations of 52 weeks (12 months) duration[.]"

223. According to the initial complaint filed by Vanda in the FDA Litigation on February 5, 2019, the FDA could not have been more clear that, at all relevant times in 2018, Vanda's failure to conduct the nine-month non-rodent toxicity study would result in a clinical hold, with Vanda alleging, in pertinent part, that:

> ***Throughout 2018, including in the Clinical Hold Letter and in Vanda's conversations with [the FDA], FDA made clear that, one way or another, Vanda would be obligated to conduct the nine-month study[.]***

224. According to the Vanda FDA Complaint, on December 21, 2018, Vanda requested a reconsideration of the partial clinical holds imposed by the FDA.

225. According to the Vanda FDA Complaint, on January 4, 2019, the FDA informed Vanda it was denying the Company's request for reconsideration.

226. Investors did not learn about the threat to Vanda's clinical testing regime for tradipitant caused by the Company's refusal to conduct a routine safety test on tradipitant until after the market closed on February 5, 2019, when, to the surprise of investors and analysts, Vanda issued a press release announcing that it had initiated the FDA Litigation, which sought, among other things, to lift the partial clinical holds. On this news, the trading price of Vanda's common stock declined $5.00, or 19.95%.

227. Analysts were deeply concerned by Defendants' decision to sue the FDA, and its related refusal to conduct a routine safety test for tradipitant. For example, in a February 6, 2019 report on Vanda, analyst Ester Rajavelu of Oppenheimer & Co. stated, in pertinent part, that:

> VNDA's announcement that it is pursuing legal action against the FDA due to a partial clinical hold restricting tradipitant dosing to 3 months ***comes as a surprise to us***. The FDA is requesting tox data from a nine month non-rodent study to allow longterm dosing in clinical trials. While management acknowledges this would be a low cost study it believes FDA's requirement to be unethical due to the euthanizing of dogs (we note other non-human mammals could also be used). While our valuation does not include tradipitant revenues, we view a lawsuit as a non-optimal strategy . . .
>
> * * *
>
> ***We note the FDA's request for nine-month tox data from non-human mammals is not unusual given gastroparesis and atopic dermatitis are chronic conditions requiring long-term therapy***.

228. In addition, in a February 6, 2019 report on Vanda, analyst Derek Archila of Stifel Nicolaus stated, in pertinent part, that:

> We believe VNDA's decision to sue the FDA for what it feels are unnecessary animal studies' and due to the company's current refusal to run these studies having resulted in a partial clinical hold on tradipitant, ***this will certainly raise questions among investors about the clinical timelines for this program and whether or not management is really focused on creating value for its shareholders***.

229. Likewise, a February 12, 2019 *Washington Business Journal* report on Vanda, which included quotes from an interview conducted by the *Washington Business Journal* with defendant Polymeropoulos that day, stated, in pertinent part, that:

> While the clinical hold doesn't affect Vanda's timing for filing an application for FDA approval at this point, it could delay progress if it's not resolved in the next few months, Polymeropoulos said. That's because the hold isn't on ongoing studies - Vanda plans to start a new phase 3 study in gastroparesis in the next few months. ***But it would postpone proposed studies to treat patients for longer than three months, a typical requirement for market authorization. "So if we were not allowed to collect this information at the time of filing, we're not going to have sufficient information to seek approval," Polymeropoulos said.***

230. Further, according to a February 14, 2019 report on Vanda by analyst Derek Archila of Stifel Nicolaus, Vanda's "shares [were] down -26% since 2/5 vs. S&P 500 which is up +1%," a result that "has largely been driven by the news of the partial clinical hold (PCH) on tradipitant and the unsealed whistleblower lawsuit[.]"

231. Vanda's refusal to conduct the necessary safety testing for tradipitant during the Class Period rendered false and misleading the repeated statements made by Defendants during the Class Period regarding the progress of Study 2301, tradipitant's future prospects given the positive results of Study 2301, and other representations in Vanda's SEC filings regarding tradipitant. By repeatedly speaking about the topic of Vanda's clinical trials for tradipitant, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that the FDA informed Vanda on the 5/15/18 Call that an extended study of tradipitant would not be possible without Vanda conducting the required safety testing, these statements omitted material information from Vanda's investors, thereby rendering Defendants' Class Period statements materially false and misleading.

MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD

232. During the Class Period, Defendants made materially false and misleading statements, and otherwise violated an obligation to disclose material information, concerning: (i) the Company's scheme to promote Fanapt off-label; (ii) the Company's scheme to promote Hetlioz off-label; (iii) Vanda's decision to forgo a routine safety study that the Company knew would result in a clinical trial hold for tradipitant; and (iv) known uncertainties, events, trends and material risks associated with Vanda's operations.

The False and Misleading Fanapt Misstatements and Omissions

233. The Class Period begins on November 4, 2015. The previous day, November 3, the Company held a conference call for analysts and investors (the "11/3/15 Call") after the market closed to discuss Vanda's financial results and performance for the third fiscal quarter of 2015 ("3Q15"). During the 11/3/15 Call, defendant Gibbs stated, in pertinent part, that:

> And when we drilled down at the individual territory level we were able to measure the promotional response based upon reach and frequency and based upon the early data it provided a strong signal confirming the promotional sensitivity of Fanapt. Based upon those data, ***we have decided to expand the Fanapt 12 to Fanapt 50 where we're going to be populating 50 of the most productive territories creating a competitive share of voice which we think we will be able to replicate the results that we saw within the Fanapt 12 and stabilize the Fanapt business exiting 2015***.

234. The statements made by defendants Gibbs and Vanda in ¶233 were materially false and misleading when made because Vanda had not "decided to expand the Fanapt 12 to Fanapt 50" to "stabilize the Fanapt business existing 2015." Instead, at all relevant times before and during the Class Period, Vanda was engaged in an off-label promotion scheme for Fanapt, and the expansion from the Fanapt 12 to the Fanapt 50 was designed to increase the scope and extent of that scheme. Accordingly, defendants Gibbs and Vanda's statements were materially false and misleading when made.

235. In addition, by speaking about the topic of expanding the sales force for Fanapt, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda's expansion from the Fanapt 12 to the Fanapt 50 was designed to increase the scope and extent of the Company's off-label promotion scheme for Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Class Period rendered this statement materially false and misleading.

236. On November 4, 2015, Vanda filed a Form 10-Q for 3Q15 (the "3Q15 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q15 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

237. By speaking about the topic of the importance of successfully commercializing Fanapt, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was using an off-label promotion scheme to commercialize Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Class Period rendered this statement materially false and misleading.

238. On November 19, 2015, defendant Polymeropoulos participated at the Jefferies Autumn Global Healthcare Conference (the "11/19/15 Conference") to discuss the Company and its business. During the 11/19/15 Conference, defendant Polymeropoulos stated, in pertinent part, that:

> Some of the side effects are -- include metabolic weight, movement disorders, ***but there is one that Fanapt/iloperidone can differentiate itself, and that is akathisia***. Akathisia is a state of inner restlessness often leading to suicidal thoughts and many times completed suicide. And that is not a symptom of schizophrenia. It is a side effect of the drugs to treat schizophrenia. Unfortunately, many of these new drugs that are offered quite a bit to patients have a mechanism of action that develops the side effect of akathisia. ***Fanapt does not have it. And on the US label, you can read that the akathisia rates for Fanapt are equal to placebo. So we believe there is a place for Fanapt in the schizophrenia market and the opportunity can be significant***.
>
> * * *
>
> We have not put commercial effort behind [Fanapt] yet. Some effort began as a pilot of 12 account managers in August. ***And now with encouraging results in the pilot, we are moving to building a 50-person sales force in the US***.

239. By speaking about the topic of Fanapt's relatively low rate of akathisia in the context of treating schizophrenia, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was using Fanapt's potential in reducing akathisia as a central part of its off-label promotion scheme for Fanapt, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Class Period rendered this statement materially false and misleading.

240. Moreover, defendant Polymeropoulos' discussion of building "a 50-person sales force in the US" above in ¶238 was materially false and misleading when made for the reasons set forth in ¶¶234-35.

241. On February 10, 2016, the Company held a conference call for analysts and investors (the "2/10/16 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2015 ("4Q15") and full year 2015 ("FY15"). During the 2/10/16 Call, defendant Polymeropoulos stated, in pertinent part, that:

> ***In late Q4, we completed the launch of a 50-person Fanapt-dedicated sales force, which is promoting Fanapt primarily to psychiatrists across the U.S***. Our goal is to stabilize the unit demand for Fanapt with this effort.

242. The statements referenced above in ¶241 were materially false and misleading for the reasons set forth in ¶¶234-35.

243. On February 12, 2016, Vanda filed its annual report on Form 10-K with the SEC for FY15 (the "2015 Form 10-K"), which was signed by defendants Polymeropoulos and Kelly, as well as the Company's directors. The 2015 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

244. The statement referenced above in ¶243 was materially false and misleading for the reasons set forth in ¶237.

245. The 2015 Form 10-K also discusses the notion that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Fanapt, stating, in pertinent part, as follows:

> ***Failure to comply with government regulations regarding the sale and marketing of our products could harm our business***.

246. The statement in ¶245 was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Fanapt could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

247. On May 4, 2016, the Company held a conference call for analysts and investors (the "5/4/16 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2016 ("1Q16"). During the 5/4/16 Call, defendant Polymeropoulos stated, in pertinent part, that:

> In the 50 territories in which we began promoting Fanapt through our sales force, we observed a significantly lower rate of demand decline as compared to non-promoted territories. As a reminder, ***we increased our field force from a 12-person pilot to a 50-person team in December of 2015***.

248. The statement referenced above in ¶247 was materially false and misleading for the reasons set forth in ¶¶234-35.

249. On May 5, 2016, Vanda filed a Form 10-Q for 1Q16 (the "1Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

250. The statement referenced above in ¶249 was materially false and misleading for the reasons set forth in ¶237.

251. The 1Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

252. The statement referenced in ¶251 above was materially false and misleading when made because, as set forth in ¶246, the risk described in the 2015 Form 10-K regarding the potential harm to Vanda from failing to comply with applicable laws and regulations in selling and marketing Fanapt was not merely prospective; it had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Fanapt.

253. On June 9, 2016, defendant Polymeropoulos participated in the Jefferies Healthcare Conference (the "6/9/16 Conference") to discuss the Company and its business. During the 6/9/16 Conference, defendant Polymeropoulos stated, in pertinent part, that:

> And for those individuals who develop this restlessness [akathisia] when taking other antipsychotics, ***we are recommending Fanapt as a second-line treatment***. As many people know, there are quite a few antipsychotics on the market and it is incredibly important to best position your drug. This is a promotionally sensitive class.
>
> And so, with that said, we initiated our promotion in April of last year initially with a pilot of about 12 reps to understand the messaging, the promotional sensitivity. ***We expanded that field force from 12 to 50 at the end of last year***, and you can see the results that we have had since bringing Fanapt back in house.

254. The statement referenced above in ¶253 that "we are recommending Fanapt as a second-line treatment [for akathisia]" was materially false and misleading because by speaking about the topic of Fanapt's status as a second line treatment, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was promoting and marketing Fanapt as a first line treatment, meaning off-label, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Class Period rendered this statement materially false and misleading.

255. The statement referenced above in ¶253 that "[w]e expanded that field force from 12 to 50 at the end of last year" was materially false and misleading for the reasons set forth in ¶¶234-35.

256. On June 21, 2016, defendant Polymeropoulos participated in the JMP Securities Life Sciences Conference (the "6/21/16 Conference") to discuss the Company and its business. During the 6/21/16 Conference, defendant Polymeropoulos stated, in pertinent part, that:

> ***We put 12 sales reps in the field last August, supplemented by another 38 in December***. So now the full 50 have been on board for the first and now second quarter. So, what we see is what you described, Jason: the beginnings of stabilizing

> that decline. Still, we see some overall decline around the country. We did an analysis in the first quarter, where the territory supported by 50 reps are significantly outperforming white space. So, we know they are doing something good. We certainly wanted to be supported and do more, stabilize the decline and eventually return to growth.
>
> * * *
>
> ***We are working on differentiation with our sales force***. We know from the US label that the rate of akathisia, a very significant side effect by some antipsychotics, is similar to placebo. ***And physicians now very quickly are becoming aware of that as well***.

257. The statement referenced above in ¶256 that "[w]e put 12 sales reps in the field last August, supplemented by another 38 in December" was materially false and misleading for the reasons set forth in ¶¶234-35.

258. The statements referenced above in ¶256 that "[w]e are working on differentiation with our sales force" and "physicians now very quickly are becoming aware of that as well" were materially false and misleading for the reasons set forth in ¶239.

259. On July 27, 2016, the Company held a conference call for analysts and investors (the "7/27/16 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2016 ("2Q16"). During the 7/27/16 Call, defendant Polymeropoulos stated, in pertinent part, that:

> And just to address, now, specifically your question, ***we're very excited about the early signs of effectiveness of our 50-people sales force***, in that, in the territories of the 50, we see based on IMS and Symphony Health a decline of less than 1% in the promoted territories. And that compares with a continuous decline in the white space. And just to give you an order of magnitude, our 50 territories attempt to address about 70% of the prescribing universe. So, the white space is 30%. And with that, ***the lesson learned is that promotion does work, and it is received well. Our sales force is doing a great job. We'll continue to try to improve our message and the effectiveness of the sales force.***

260. The statements referenced above in ¶259 that "we're very excited about the early signs of effectiveness of our 50-people sales force," "our sales force is doing a great job," and

"[w]e'll continue to try to improve our message and the effectiveness of the sales force" were materially false and misleading for the reasons set forth in ¶¶234-35.

261. On July 28, 2016, Vanda filed a Form 10-Q for 2Q16 (the "2Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

262. The statement referenced above in ¶261 was materially false and misleading for the reasons set forth in ¶237.

263. The 2Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

264. The statement referenced above in ¶263 was materially false and misleading for the reasons set forth in ¶246.

265. On November 2, 2016, the Company held a conference call for analysts and investors (the "11/2/16 Call") to discuss Vanda's financial results and performance for the third fiscal quarter of 2016 ("3Q16"). During the 11/2/16 Call, in response to an analyst's question about how the clinical profile of Fanapt fits into other possible indications for Fanapt being pursued by the Company, defendant Polymeropoulos stated, in pertinent part, that:

> Just before I answer this question, just to remind everybody that Fanapt is approved for the indication of schizophrenia in adults in the US. I refer everybody for a full discussion of efficacy and safety to www.fanapt.com.
>
> * * *
>
> So we believe ***that Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication***, primarily because of

> tolerability; and specifically, that specific schizophrenia patient that needs to switch and has experienced drug-induced akathisia on another drug may be actually a very well-suited patient for Fanapt.
>
> * * *
>
> ***We, of course, are always interested in pediatric applications***. We know that two other agents in the antipsychotic space have been developed for certain symptoms of irritability in children with autism, and that is an indication part of the long-term planning for a pediatric indication.

266. The statement referenced above in ¶265 that "Fanapt, in patients with schizophrenia, will be a drug that will be used once patients switch from another medication" was materially false and misleading for the reasons set forth in ¶¶237, 239, 254.

267. The statements referenced above in ¶265 that "[w]e, of course, are always interested in pediatric applications [for Fanapt," Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that the Company's off-label promotion scheme for Fanapt involved marketing it to pediatric patients, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Fanapt during the Class Period rendered this statement materially false and misleading.

268. On November 3, 2016, Vanda filed a Form 10-Q for 3Q16 (the "3Q16 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

269. The statement referenced above in ¶268 was materially false and misleading for the reasons set forth in ¶237.

270. The 3Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

271. The statement referenced above in ¶270 was materially false and misleading for the reasons set forth in ¶246.

272. On February 15, 2017, the Company held a conference call for analysts and investors (the "2/15/17 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2016 ("4Q16") and full year 2016 ("FY16"). During the 2/15/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> So as we had previously communicated, ***the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency***. And we believe that the new sales force will be trained and ready to detail physicians by the end of this quarter

273. The statement referenced above in ¶272 that "the plan for this quarter is to expand the sales force from around 50 sales reps last year to about 120, increasing, therefore, both reach and ability of call frequency" was materially false and misleading for the reasons set forth in ¶¶234-35.

274. On February 17, 2017, Vanda filed its annual report on Form 10-K with the SEC for FY16 (the "2016 Form 10-K"), which was signed by defendants Polymeropoulos and Kelly, as well as the Company's directors. The 2016 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

275. The statement referenced above in ¶274 was materially false and misleading for the reasons set forth in ¶237.

276. The 2016 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and marketing Fanapt was merely speculative, stating, in pertinent part, as follows:

> ***Failure to comply with government regulations regarding the sale and marketing of our products could harm our business***.

277. The statement referenced above in ¶276 was materially false and misleading for the reasons set forth in ¶246.

278. On March 21, 2017, defendant Polymeropoulos participated in the Oppenheimer Healthcare Conference (the "3/21/17 Conference") to discuss the Company and its business. During the 3/21/17 Conference, defendant Polymeropoulos stated, in pertinent part, that:

> ***Fanapt is considered in the US a second line treatment for schizophrenia***.

279. The statement referenced above in ¶278 was materially false and misleading for the reasons set forth in ¶254.

280. On May 2, 2017, the Company held a conference call for analysts and investors (the "5/2/17 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2017 ("1Q17"). During the 5/2/17 Call, defendant Reverberi stated, in pertinent part, that:

> During the first quarter of 2017, we successfully completed the expansion of the Fanapt U.S. field sales team, and ***the full team is now in the field promoting the benefits of Fanapt for adult schizophrenia patients with a significant increase in frequency to our target physicians audience***.

281. The statement referenced above in ¶280 was materially false and misleading for the reasons set forth in ¶¶234-35.

282. On May 3, 2017, Vanda filed a Form 10-Q for 1Q17 (the "1Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that:

"***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

283. The statement referenced above in ¶282 was materially false and misleading for the reasons set forth in ¶237.

284. The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016***.

285. The statement referenced above in ¶284 was materially false and misleading for the reasons set forth in ¶246.

286. On August 2, 2017, the Company held a conference call for analysts and investors (the "8/2/17 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2017 ("2Q17"). During the 8/2/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> After successfully completing the expansion of our Fanapt field sales team in the first quarter of 2017, ***the full team has started promoting the benefits of Fanapt for adult schizophrenia patients with an expanded reach and frequency***.

287. The statement referenced above in ¶286 was materially false and misleading for the reasons set forth in ¶¶234-35, 239, 254, 267.

288. On August 3, 2017, Vanda filed a Form 10-Q for 2Q17 (the "2Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

289. The statement referenced above in ¶288 was materially false and misleading for the reasons set forth in ¶237.

290. The 2Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016***.

291. The statement referenced above in ¶290 was materially false and misleading for the reasons set forth in ¶246.

292. On September 13, 2017, defendant Kelly participated at the Morgan Stanley Healthcare Conference (the "9/13/17 Conference") to discuss the Company and its business. During the 9/13/17 Conference, defendant Kelly stated, in pertinent part, that:

> But as we have put more effort behind the product, including what we just did right now, we are now initially seeing the slowing of the decline in what appears to be the degree of stabilization, what we're looking for is growth. ***And it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth***.

293. The statement referenced above in ¶292 that "it's our expectation that the reps we have put on board are going to have the ability to return Fanapt back to growth" was materially false and misleading for the reasons set forth in ¶¶234-35, 239, 254, 267.

294. On November 8, 2017, Vanda filed a Form 10-Q for the third fiscal quarter of 2017 ("3Q17") (the "3Q17 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 3Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

295. The statement referenced above in ¶294 was materially false and misleading for the reasons set forth in ¶237.

296. The 3Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016.

297. The statement referenced above in ¶296 was materially false and misleading for the reasons set forth in ¶246.

298. On February 15, 2018, Vanda filed its annual report on Form 10-K with the SEC for the full year of 2017 ("FY17") (the "2017 Form 10-K"), which was signed by defendants Polymeropoulos and Kelly, as well as the Company's directors. The 2017 Form 10-K discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . ."

299. The statement referenced above in ¶298 was materially false and misleading for the reasons set forth in ¶237.

300. The 2017 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Fanapt was merely speculative, stating, in pertinent part, as follows:

Failure to comply with government regulations regarding the sale and marketing of our products could harm our business.

301. The statement referenced above in ¶300 was materially false and misleading for the reasons set forth in ¶246.

302. On May 2, 2018, the Company held a conference call for analysts and investors (the "5/2/18 Call") to discuss Vanda's financial results and performance for the first fiscal quarter of 2018 ("1Q18"). During the 5/2/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

Our sales team continues making progress in introducing Fanapt as an additional option in treating adult patients with schizophrenia.

303. The statement referenced above in ¶302 was materially false and misleading for the reasons set forth in ¶¶234-35, 239, 254, 267.

304. On May 2, 2018, Vanda filed a Form 10-Q for 1Q18 (the "1Q18 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 1Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

305. The statement referenced above in ¶304 was materially false and misleading for the reasons set forth in ¶237.

306. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

307. The statement referenced above in ¶306 was materially false and misleading for the reasons set forth in ¶246.

308. On August 1, 2018, the Company held a conference call for analysts and investors (the "8/1/18 Call") to discuss Vanda's financial results and performance for the second fiscal quarter of 2018 ("2Q18"). During the 8/1/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> I also want to remind that in June, we undertook a reorganization of the Fanapt sales force that promote HPI, and that was a very significant reorganization. And we're in the midst of hiring in full the sales force back up to a number of 115 after we changed about 35-or-so sales representatives. So we do expect that this reorganization will affect the production of new scripts during that reorganization, but we do not expect the reorganization to affect the overall performance of the third quarter or beyond. ***And we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and HETLIOZ***.

309. The statement referenced above in ¶308 that "we believe that this will strengthen, actually, our presence in the psychiatrist office in the promotion of both Fanapt and Hetlioz" was materially false and misleading for the reasons set forth in ¶¶234-35, 239, 254, 267.

310. On August 2, 2018, Vanda filed a Form 10-Q for 2Q18 (the "2Q18 Form 10-Q"), which was signed by defendants Polymeropoulos and Kelly. The 2Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

311. The statement referenced above in ¶310 was materially false and misleading for the reasons set forth in ¶237.

312. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

313. The statement referenced above in ¶312 was materially false and misleading for the reasons set forth in ¶246.

314. On November 7, 2018, Vanda filed the 3Q18 Form 10-Q, which was signed by defendants Polymeropoulos and Kelly. The 3Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Fanapt, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize . . . Fanapt®*** . . . ."

315. The statement referenced above in ¶314 was materially false and misleading for the reasons set forth in ¶237.

316. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

317. The statement referenced above in ¶316 was materially false and misleading for the reasons set forth in ¶246.

The False and Misleading Hetlioz Misstatements and Omissions

318. The 3Q15 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

319. By speaking about the topic of the importance of successfully commercializing Hetlioz, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was using an off-label promotion scheme to commercialize Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Class Period rendered this statement materially false and misleading.

320. The 2015 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

321. The statement referenced above in ¶320 was materially false and misleading for the reasons set forth in ¶319.

322. 2015 Form 10-K also discusses the notion that Vanda could fail to comply with applicable laws and regulations regarding selling and promoting Hetlioz, stating, in pertinent part, as follows:

> ***Failure to comply with government regulations regarding the sale and marketing of our products could harm our business***.

323. The statement in ¶322 was materially false and misleading because it failed to disclose that it was not merely possible that failing to comply with applicable laws and regulations regarding selling and marketing Hetlioz could disrupt the Company's business and financial performance; this risk had already materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Hetlioz.

324. The 1Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

325. The statement referenced above in ¶324 was materially false and misleading for the reasons set forth in ¶319.

326. The 1Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

327. The statement referenced in ¶326 above was materially false and misleading when made because, as set forth in ¶323, the risk described in the 2015 Form 10-K regarding the potential harm to Vanda from failing to comply with applicable laws and regulations regarding selling and promoting Hetlioz was not merely prospective; it had materialized because Vanda was actively and knowingly engaged in an off-label promotion scheme for Hetlioz.

328. The 2Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

329. The statement referenced above in ¶328 was materially false and misleading for the reasons set forth in ¶319.

330. The 2Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

331. The statement referenced above in ¶330 was materially false and misleading for the reasons set forth in ¶323.

332. The 3Q16 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

333. The statement referenced above in ¶332 was materially false and misleading for the reasons set forth in ¶319.

334. The 3Q16 Form 10-Q provided no update to the Company's risk factors since the filing of the 2015 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2015***.

335. The statement referenced above in ¶334 was materially false and misleading for the reasons set forth in ¶323.

336. During the 2/15/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> On HETLIOZ, our US commercial business is in its third year and continues to add new patients. ***Our HETLIOZ team is focused on driving growth by creating awareness about non-24 and assisting patients to learn more about treatment options***.

337. By speaking about the topic of driving growth for Hetlioz, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was using an off-label promotion scheme to drive growth for Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Class Period rendered this statement materially false and misleading.

338. The 2016 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

339. The statement referenced above in ¶388 was materially false and misleading for the reasons set forth in ¶319.

340. The 2016 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Hetlioz was merely speculative, stating, in pertinent part, as follows:

> ***Failure to comply with government regulations regarding the sale and marketing of our products could harm our business***.

341. The statement referenced above in ¶340 was materially false and misleading for the reasons set forth in ¶323.

342. During the 5/2/17 Call, defendant Reverberi stated, in pertinent part, that:

> ***The fundamentals of our HETLIOZ business remains strong***, as we consistently add new patients on therapy and are seeing early signs of improved persistency associated with the recent change to our specialty pharmacy network.

343. The statement referenced above in ¶342 that the "fundamentals of our Hetlioz business remains strong" was materially false and misleading for the reasons set forth in ¶337.

344. The 1Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

345. The statement referenced above in ¶344 was materially false and misleading for the reasons set forth in ¶319.

346. The 1Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016***.

347. The statement referenced above in ¶346 was materially false and misleading for the reasons set forth in ¶323.

348. During the 8/2/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> ***[I]n July, the Fanapt US field force team began promoting HETLIOZ to psychiatrists.*** We're confident that this will represent a great opportunity to both expand the number of Non-24 patients who can benefit from HETLIOZ and reinforce the partnership with the psychiatrists by bringing solutions to patients with Non-24.

349. By speaking about Vanda's implementation of the HPI, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda had been marketing Hetlioz to psychiatrists since at least November 2015 and that such efforts centered on the off-label marketing of Hetlioz, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the Company's efforts to market and sell Hetlioz during the Class Period rendered this statement materially false and misleading.

350. The 2Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

351. The statement referenced above in ¶350 was materially false and misleading for the reasons set forth in ¶319.

352. The 2Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016***.

353. The statement referenced above in ¶352 was materially false and misleading for the reasons set forth in ¶323.

354. On November 7, 2017, the Company held a conference call for analysts and investors (the "11/7/17 Call") to discuss Vanda's financial results and performance for 3Q17. During the 11/7/17 Call, defendant Polymeropoulos stated, in pertinent part, that:

> ***So we did have experience before with sighted patients with Non-24 that have spontaneously come into the program***. And what we've seen in the past is that payers block more scripts that come out of sighted Non-24 patients than blind. Of course, we do not agree with that attitude; but nonetheless, it is a fact.

355. The statement referenced above in ¶354 that "we did have experience before with sighted patients with Non-24 that have spontaneously come into the program" was materially false and misleading for the reasons set forth in ¶349.

356. The 3Q17 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

357. The statement referenced above in ¶356 was materially false and misleading for the reasons set forth in ¶319.

358. The 3Q17 Form 10-Q provided no update to the Company's risk factors since the filing of the 2016 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2016***.

359. The statement referenced above in ¶358 was materially false and misleading for the reasons set forth in ¶323.

360. On February 14, 2018, the Company held a conference call for analysts and investors (the "2/14/18 Call") to discuss Vanda's financial results and performance for the fourth fiscal quarter of 2017 ("4Q17") and FY17. During the 2/14/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> We fully launched HPI with a full sales force promoting to psychiatrists beginning of October of 2017. So in this 3 months, over the last quarter, we saw a significant increase of the total scripts per month, which have more than doubled as compared to the monthly scripts seen before with the program which was based primarily on the Patient Directed Physician program, the PDP. ***Just to clarify, Jason, in the past, some of the scripts were coming from sighted people as well. The difference is that in the HPI initiative, most of the patients are sighted***.

361. The statements referenced above in ¶360 that "in the past, some of the scripts were coming from sighted people as well" and the "difference is that in the HPI initiative, most of the patients are sighted" were materially false and misleading for the reasons set forth in ¶349.

362. The 2017 Form 10-K discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

363. The statement referenced above in ¶362 was materially false and misleading for the reasons set forth in ¶319.

364. The 2017 Form 10-K also discusses that any failure by Vanda to comply with applicable laws and regulations regarding selling and promoting Fanapt was merely speculative, stating, in pertinent part, as follows:

> ***Failure to comply with government regulations regarding the sale and marketing of our products could harm our business***.

365. The statement referenced above in ¶364 was materially false and misleading for the reasons set forth in ¶323.

366. During the 5/2/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> ***The HETLIOZ to Psychiatry Initiative, which was launched late last year, continues to drive an acceleration in new patient demand***. In the first quarter of 2018, we achieved a new all-time high number of new HETLIOZ intakes, these are the prescriptions and patient starts, as well as a new all-time high number of patients on therapy. ***The positive response from the psychiatric community is a confirmation of the significant unmet medical need for patients with Non-24***.

367. The statements referenced above in ¶366 that "[HPI] continues to drive an acceleration in new patient demand" and the "positive response from the psychiatric community is a confirmation of the significant unmet medical need for patients with Non-24" were materially false and misleading for the reasons set forth in ¶349.

368. The 1Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

369. The statement referenced above in ¶368 was materially false and misleading for the reasons set forth in ¶319.

370. The 1Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

371. The statement referenced above in ¶370 was materially false and misleading for the reasons set forth in ¶323.

372. On May 9, 2018, defendant Kelly participated in the Deutsche Bank Healthcare Conference (the "5/9/18 Conference") to discuss the Company and its business. During the 5/9/18 Conference, defendant Kelly stated, in pertinent part, that:

> In the U.S., the indication is Non-24 irrespective of vision status. And this is of importance because most recently in the U.S., ***we launched an initiative, HETLIOZ to psychiatry initiative, where individuals with psychiatric comorbidities, many of whom may be sighted, have also begun to benefit from HETLIOZ. And of course, it's all within our U.S.-approved label.***

373. The statements referenced above in ¶372 that "many of whom may sighted, have also begun to benefit from Hetlioz" and "of course, it's all within our U.S.-approved label" were materially false and misleading for the reasons set forth in ¶349.

374. The 2Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

375. The statement referenced above in ¶374 was materially false and misleading for the reasons set forth in ¶319.

376. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

377. The statement referenced above in ¶376 was materially false and misleading for the reasons set forth in ¶323.

378. On September 12, 2018, defendant Kelly participated in the Morgan Stanley Healthcare Conference (the "9/12/18 Conference") to discuss the Company and its business. During the 9/12/18 Conference, defendant Kelly stated, in pertinent part, that:

> And I'd say that this core blind business has been a great methodical growth story. But something changed last year in the fourth quarter. And what changed was a new initiative where we began targeting sighted individuals with psychiatric comorbidities who had Non-24. And what start us down this path was the work we were doing with Fanapt or atypical antipsychotic, where we're calling on 10,000 psychiatrists. ***We decided after expanding our Fanapt field force last year to introduce HETLIOZ to that group, and the response has been incredible***. We saw a more than doubling of our scripts, and we shared with investors, both in the first quarter, second quarter, that we had all-time highs of both scripts and new patient starts, and it's being driven, the majority of it, by this sighted strategy. And so fairly unusual to have a product 5 years in that is continuing its core methodical growth and then add on top of it a new diversified approach to grow in the business.
>
> * * *
>
> And when we developed HETLIOZ for Non-24, our focus was on totally blind individuals, these individuals who lost that light perception, along with it, lost what is considered to be the standard mechanism to reset your body clock every day.

379. The statement referenced above in ¶378 that "[w]e decided after expanding our Fanapt field force last year to introduce Hetlioz to that group, and the response has been incredible" was materially false and misleading for the reasons set forth in ¶349.

380. On November 7, 2018, the Company held a conference call for analysts and investors (the "11/7/18 Call") to discuss Vanda's financial results and performance for 3Q18. During the 11/7/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> HPI now is a year old, the program, and ***what is impressive is the significant, continuous new demand, new scripts written by psychiatrists in the HPI initiative***. While Jim is correct that the PDP part of the business, which is mostly blind individuals, these are people we have opted into the database, continues to be a big driver and source. However, in new demand, and that is -- the definition of demand here is new scripts written, HPI continues to significantly outstrip the demand of

> PDP. So with that, one would have expected to actually saw even bigger growth than the 34%, which is nonetheless impressive. So why we have not seen even bigger growth? The HPI business, as we characterized before, has created a demand 2 to 3x higher than the PDP. However, the resistance by insurers on filling out the scripts, although it is the only indication and there is no other drug available for these patients, continues to be strong. We're working with our patients, we're working with the doctors to impress upon these insurers that this drug is necessary. We're making a lot of progress. But if we were to match the demand generated with fill, of course, these numbers would have been much, much bigger.

381. The statement referenced above in ¶380 that "what is impressive is the significant, continuous new demand, new scripts written by psychiatrists in the HPI initiative" was materially false and misleading for the reasons set forth in ¶349.

382. The 3Q18 Form 10-Q discusses the importance to Vanda of successfully commercializing Hetlioz, and stated, in pertinent part, that: "***Our ability to generate meaningful product sales and achieve profitability largely depends on our ability to successfully commercialize HETLIOZ®*** . . . ."

383. The statement referenced above in ¶382 was materially false and misleading for the reasons set forth in ¶319.

384. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

385. The statement referenced above in ¶384 was materially false and misleading for the reasons set forth in ¶323.

The False and Misleading Tradipitant Misstatements and Omissions

386. On August 1, 2018, the Company issued a press release, which was also filed on Form 8-K, that provided Vanda's 2Q18 financial results and performance to analysts and investors (the "8/1/18 Form 8-K"). The 8/1/18 Form 8-K stated, in pertinent part, that:

> ***A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected by the end of 2018***.

387. By speaking about the status of the 2301 Study, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda knew its unwillingness to conduct a routine non-rodent study to ensure tradipitant's safety for humans meant that the FDA would impose a clinical hold on a necessary extension of the 2301 Study, this statement omitted material information from Vanda's investors, thereby rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of tradipitant clinical trials during the Class Period rendered this statement materially false and misleading.

388. During the 8/1/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> The recruitment efforts in the tradipitant gastroparesis clinical study are now working. We can now report that as of today, 110 patients have been randomized in the study. With a number of patients in screening, ***we're now on target to randomize approximately 150 patients and expect to report results by year-end***.

389. The statement referenced above in ¶388 was materially false and misleading for the reasons set forth in ¶387.

390. The 2Q18 Form 10-Q stated, in pertinent part, that:

> ***A tradipitant clinical study for the treatment of gastroparesis is ongoing. Results are expected by the end of 2018***.

391. The statements referenced above in ¶390 were materially false and misleading for the reasons set forth in ¶387.

392. The 2017 Form 10-K contained a prospective risk warning pertaining to clinical trial results. The 2017 Form 10-K states, in pertinent part, that:

> In the U.S., the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act, as amended, and implements regulations. ***If we fail to comply with the applicable requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include*** the FDA's refusal to approve pending applications, withdrawals of approvals, ***clinical holds***, warning letters,

> product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any such sanction could have a material adverse effect on our business.

393. The 2Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

> ***There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017***.

394. The statement referenced above in ¶393 from the 2Q18 Form 10-Q was materially false and misleading because Vanda was informed by the FDA on the 5/15/18 Call that the FDA would impose a clinical hold on an extension study of the 2301 Study if Vanda did not complete the required non-rodent toxicity study to ensure that tradipitant is safe to use in humans. By falsely claiming that "no material changes" to Vanda's risk factors had occurred during 2Q18 with respect to complying with FDA regulations, this statement was materially false and misleading to investors because Vanda knew all along that it would not conduct the required non-rodent study and that this refusal would trigger a clinical trial hold.

395. On November 7, 2018, the Company issued a press release, which was also filed on Form 8-K, that provided Vanda's 3Q18 financial results and performance to analysts and investors (the "11/718 Form 8-K"). The 11/7/18 Form 8-K stated, in pertinent part, that:

> ***Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018***.

396. The statements referenced above in ¶395 were materially false and misleading for the reasons set forth in ¶387.

397. During the 11/7/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> Tradipitant, the most exciting clinical milestone for Vanda, is coming up in the next few weeks. ***And it will come from the top line results of our first Phase II study of tradipitant in gastroparesis***. Gastroparesis is a common and poorly treated disorder with a significant unmet medical need affecting about 6 million people in the U.S. alone. ***Our Phase II study, of which we'll report the results next month, is a 150-***

patient, 2-arm, double-blind tradipitant versus placebo 85-milligram twice a day of tradipitant to evaluate the ability of the drug to improve symptoms of gastroparesis over a period of 4 weeks.

398. The statements referenced above in ¶397 that "it will come from the top line results of our first Phase II study of tradipitant in gastroparesis" and "[o]ur Phase II study . . ." were materially false and misleading for the reasons set forth in ¶387.

399. The 3Q18 Form 10-Q stated, in pertinent part, that:

Enrollment in the clinical study of tradipitant in gastroparesis is complete. Results are expected by the end of 2018.

400. The statements referenced above in ¶399 were materially false and misleading for the reasons set forth in ¶387.

401. The 3Q18 Form 10-Q provided no update to the Company's risk factors since the filing of the 2017 Form 10-K, and stated, in pertinent part, that:

There have been no material changes in our risk factors subsequent to the filing of our annual report on Form 10-K for the fiscal year ended December 31, 2017.

402. The statement referenced above in ¶401 was materially false and misleading for the reasons set forth in ¶394.

403. The 12/3/18 Form 8-K stated, in pertinent part, that:

Vanda expects to meet with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis.

404. By speaking about Vanda's interactions with the FDA to discuss future clinical trials for tradipitant related to gastroparesis, Defendants had a duty to speak fully and truthfully. Because Defendants failed to disclose that Vanda was informed by the FDA on the 5/15/18 Call that the Company's refusal to conduct a nine-month non-rodent toxicity study to ensure that tradipitant is safe in humans meant that the FDA would impose a clinical hold on any tradipitant trial over three months in duration, this statement omitted material information from Vanda's investors, thereby

rendering this statement materially false and misleading. Defendants' failure to adequately disclose an accurate portrayal of the status of tradipitant clinical trials during the Class Period rendered this statement materially false and misleading.

405. On December 3, 2018, defendants Polymeropoulos and Kelly also hosted a conference call with analysts and investors to announce positive results from the 2301 Study (the "12/3/18 Call"). During the 12/3/18 Call, defendant Polymeropoulos stated, in pertinent part, that:

> Finally, we believe that if these robust efficacy results with a well-tolerated chronic treatment safety profile are further confirmed in future studies, tradipitant has the potential to become a first-line pharmacological option in the treatment of patients with gastroparesis and the first such agent in 40 years. The detailed results of the study are expected to be presented in our cabin meetings and peer-reviewed publications. ***We will also be meeting with regulatory authorities in the near future to further define and confirm the path towards registration of tradipitant in the treatment of patients with gastroparesis***.
>
> * * *
>
> Pete, certainly, we want to continue to evaluate the effectiveness of the drug in the broad population of gastroparetic patients. However, I would say while we have some very good ideas of potential designs and population of patients, we need to spend a little more time understanding these study results, ***but also sit down with key opinion leaders, investigators, and certainly, the Food and Drug Administration to find out the fastest to market.*** And the reason for that is we recognize that what tradipitant has shown in this Phase II study, can be an extremely useful therapeutic tool for patients.
>
> * * *
>
> Analyst (Esther Rajavelu, Oppenheimer): "And then my last question. Are you -- do you anticipate having to do a long-term safety study on -- in the gastroparesis population given the chronic nature of the condition and the treatment?
>
> Defendant Polymeropoulos: "Absolutely, I would be very appropriate to do so. ***And in fact, we have a 12-month protocol, which we'll be implementing shortly***.

406. The statements referenced above in ¶405 that "[w]e will also be meeting with regulatory authorities in the near future . . ." and "sit down with . . . the Food and Drug

Administration to find out the fastest to market" were materially false and misleading for the reasons set forth in ¶404.

407. The statement referenced above in ¶405 that "we have a 12-month protocol, which we'll be implementing shortly" was materially false and misleading when made because it misrepresented the following facts, which Defendants knew, or recklessly disregarded:

(a) Vanda could not implement a 12-month protocol for tradipitant shortly because the FDA told Vanda on the 5/15/18 Call that the Company had to first conduct a nine-month non-rodent study to ensure that tradipitant is safe to use in humans;

(b) Vanda was unwilling at all relevant times to conduct the required nine-months safety study; and

(c) Vanda intended to sue the FDA if the FDA placed the expected clinical trial holds on any tradipitant studies over three months in length.

Omissions Based on Violations of Items 303 and 503

Item 303

408. The SEC created specific rules governing the content of disclosures by public companies in their filings with the SEC. SEC Regulation S-K requires that every Form 10-K and Form 10-Q filing contain "Management's Discussion and Analysis of Financial Condition and Results of Operations" ("MD&A"), drafted in compliance with Item 303 of Regulation S-K, 17 C.F.R. §229.303. The MD&A requirements are intended to provide material historical and prospective textual disclosures that enable investors and others to assess the financial condition and results of operations of a company, with emphasis on that company's prospects for the future.

409. Pursuant to Item 7 of Form 10-K and Item 2 of Form 10-Q, Vanda's Class Period SEC filings were required to furnish certain information required under Item 303(a)(3) of Regulation S-K including, among other things:

(a) Describe any unusual or infrequent events or transactions or any significant economic changes that materially affected the amount of reported income from continuing operations and, in each case, indicate the extent to which income was so affected. In addition, describe any other significant components of revenues or expenses that, in the registrant's judgment, should be described in order to understand the registrant's results of operations; and

(b) Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.

410. Regulation S-K also states that "[t]he discussion and analysis [section] shall focus specifically on material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition."

411. The following were known trends, events, or uncertainties that were having, and were reasonably likely to have, a negative impact on the Company's continuing operations and, therefore, were required to be disclosed by Defendants pursuant to Item 303 in the 3Q15 Form 10-Q, the 2015 Form 10-K, the 1Q16 Form 10-Q, the 2Q16 Form 10-Q, the 3Q16 Form 10-Q, the 2016 Form 10-K, the 1Q17 Form 10-Q, the 2Q17 Form 10-Q, the 3Q17 Form 10-Q, the 2017 Form 10-K, the 1Q18 Form 10-Q, the 2Q18 Form 10-Q, and the 3Q18 Form 10-Q:

(a) that Vanda's efforts to commercialize Fanapt were centered on an off-label promotion scheme; and

(b) that Vanda's efforts to commercialize Hetlioz were centered on an off-label promotion scheme.

412. In addition to the known trends, events, or uncertainties listed in ¶411 above, the following known trend, event, or uncertainty was having, and was reasonably likely to have, an impact on the Company's continuing operations and, therefore, was required to be disclosed by Defendants pursuant to Item 303 in the 2Q18 Form 10-Q and the 3Q18 Form 10-Q, but was not:

(a) that Vanda's unwillingness to conduct a routine non-rodent study to ensure tradipitant's safety for humans meant that the FDA would impose a clinical hold on any studies of tradipitant in excess of three months, thereby jeopardizing or delaying the prospect of tradipitant obtaining FDA approval.

413. The foregoing facts were required to be disclosed pursuant to Item 303 because they were, among other things: (i) "material events and uncertainties known to management that would cause reported financial information not to be necessarily indicative of future operating results or of future financial condition;" (ii) "known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations;" and (iii) "unusual or infrequent events or transactions or [] significant economic changes that [were] materially affect[ing] the amount of reported income from continuing operations."

Item 503

414. Pursuant to Item 1A of Form 10-K, Vanda's Class Period Forms 10-K were required to furnish certain information pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.503], including, among other things, a "discussion of the most significant factors that make the [securities] speculative or risky."

415. Pursuant to Item 1A of Form 10-Q, Vanda's Class Period Forms 10-Q were required to "[s]et forth any material changes from risk factors as previously disclosed" in Vanda's 2015 Form 10-K pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.503].

416. Defendants failed to comply with Item 503 by failing to adequately disclose risk factors or material changes in risk factors in these SEC filings.

417. Specifically, as required under Item 503, Defendants failed to disclose in the 3Q15 Form 10-Q, the 2015 Form 10-K, the 1Q16 Form 10-Q, the 2Q16 Form 10-Q, the 3Q16 Form 10-Q, the 2016 Form 10-K, the 1Q17 Form 10-Q, the 2Q17 Form 10-Q, the 3Q17 Form 10-Q, the 2017 Form 10-K, the 1Q18 Form 10-Q, the 2Q18 Form 10-Q, and the 3Q18 Form 10-Q the following risks, or material changes in risks:

(a) that Vanda's efforts to commercialize Fanapt were centered on an off-label promotion scheme; and

(b) that Vanda's efforts to commercialize Hetlioz were centered on an off-label promotion scheme.

418. In addition to the undisclosed material risks listed in ¶417 above, the following material risk was required to be disclosed by Defendants pursuant to Item 503 in the 2Q18 Form 10-Q and the 3Q18 Form 10-Q, but was not:

(a) that Vanda's unwillingness to conduct a routine non-rodent study to ensure tradipitant's safety for humans meant that the FDA would impose a clinical hold on any studies of tradipitant in excess of three months, thereby jeopardizing or delaying the prospect of tradipitant obtaining FDA approval.

ADDITIONAL SCIENTER ALLEGATIONS

419. As alleged herein, Vanda and the Individual Defendants acted with scienter in that they knew, or recklessly disregarded, that the public documents and statements issued or

disseminated in the name of the Company were materially false and misleading; knew, or recklessly disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly, or recklessly, and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

420. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Vanda, their control over, and/or receipt and/or modification of Vanda's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Vanda, participated in the fraudulent scheme alleged herein.

421. Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

422. The Individual Defendants were each executive officers of Vanda during the Class Period. Based on their roles at Vanda, each of the Individual Defendants would have been involved with, or knowledgeable about, the wrongdoing alleged herein, which centers on the sole sources of the Company's revenue during the Class Period (Fanapt and Hetlioz) and the Company's most important pipeline drug (tradipitant).

423. At a minimum, Defendants failed to review or check information that they had a duty to monitor, or ignored obvious signs that their statements were materially false and misleading or contained material omissions. Given the nature and extent of the problems at Vanda, Defendants knew, or recklessly disregarded, the extent and scope of their statements during the Class Period.

424. Likewise, the Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential proprietary information concerning the Company and its business, operations, financial statements, and financial condition, as alleged herein. The Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.

425. The allegations above also establish a strong inference that Vanda, as an entity, acted with corporate scienter throughout the Class Period because its officers, management, and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing Vanda's true operating condition and present and expected financial performance from investors. By concealing these material facts from investors, Vanda maintained and/or increased its artificially inflated common stock price throughout the Class Period.

426. As executives of Vanda, the Individual Defendants are all candidates for imputing corporate scienter to Vanda.

427. In addition, as executives and/or senior managers of Vanda, James, Griffin, Holland, and Arnold are also candidates for imputing corporate scienter to Vanda.

428. As a consultant to Vanda and a direct report to defendant Polymeropoulos, Ramirez is also a candidate for imputing corporate scienter to Vanda.

LOSS CAUSATION/ECONOMIC LOSS

429. As detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Vanda's common stock and operated as a fraud or deceit on Class Period purchasers of the Company's common stock. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the trading price of Vanda's common stock fell precipitously as the artificial inflation was removed.

430. As a result of their purchases of Vanda common stock during the Class Period, Lead Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws. Defendants' false and misleading statements had the intended effect and caused the Company's common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as $31.47 per share on December 3, 2018, the highest closing price achieved by the Company since January 2007.

431. On February 5, 2019, after the close of the trading day, Vanda issued a press release and announced, among other things, that the Company had initiated the FDA Litigation because the FDA had issued clinical trial holds for tradipitant studies. The next day, February 6, Vanda filed the February 5 press release with the SEC on Form 8-K.

432. In response to the aftermarket revelations on February 5, 2019, the trading price of Vanda's common stock declined from a closing price of $25.06 per share on February 5, to a closing price of $20.06 per share on February 6 – a decline of $5.00 per share, or 19.95%. The trading volume was unusually high, with trading volume of approximately 3 million shares traded, more than 4.3 times the average daily trading volume over the preceding year.

433. Then, during the trading day on February 11, 2019, Aurelius Value published a report entitled "Vanda: In the Land of the Blind, The One-Eyed Man is King," (the "Aurelius Report") that, among other things, publicly disclosed for the first time Vanda's off-label promotion scheme for Fanapt and Hetlioz.

434. In response to the revelations on February 11, 2019, the trading price of Vanda's common stock declined from an opening price of $19.05 per share on February 11 to a closing price of $18.00 per share on February 11 – a decline of $1.05 per share, or 5.51%. The trading volume was unusually high, with trading volume of approximately 4.5 million shares traded, more than 6.4 times the average daily trading volume over the preceding year.

435. As shown above, the timing and magnitude of the price declines in Vanda's common stock negate any inference that the losses suffered by Lead Plaintiff and the Class were caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraud.

CLASS ACTION ALLEGATIONS

436. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all purchasers of the common stock of Vanda during the Class Period, inclusive, and who were damaged thereby (the "Proposed Class"). Excluded from the Proposed Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

437. The members of the Proposed Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Vanda common stock was actively traded on the NASDAQ. While the exact number of Proposed Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are

hundreds, if not thousands, of members in the Proposed Class. Record owners and other members of the Proposed Class may be identified from records maintained by Vanda and/or its transfer agent and may be notified of the pendency of this action by mail or by electronic mail, using the form of notice similar to that customarily used in securities class actions.

438. Lead Plaintiff's claims are typical of the claims of the members of the Proposed Class as all members of the Proposed Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

439. Lead Plaintiff will fairly and adequately protect the interests of the members of the Proposed Class and has retained counsel competent and experienced in class and securities litigation.

440. Common questions of law and fact exist as to all members of the Proposed Class and predominate over any questions solely affecting individual members of the Proposed Class. Among the questions of law and fact common to the Proposed Class are:

(a) whether statements made by Defendants misrepresented material facts about the business, operations, and management of Vanda;

(b) whether Defendants failed to disclose material facts in discussing the business, operations, and management of Vanda, making those statements materially false and misleading;

(c) whether the federal securities laws were violated by Defendants' acts or omissions as alleged herein;

(d) whether the price of Vanda stock was artificially inflated during the Class Period; and

(e) to what extent the members of the Proposed Class have sustained damages and the proper measure of damages.

441. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Proposed Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

NO SAFE HARBOR

442. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false statements challenged herein. Many of the statements challenged herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, no meaningful cautionary statements identified important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made.

APPLICATION OF PRESUMPTION OF RELIANCE:
THE *BASIC* AND *AFFILIATED UTE* PRESUMPTIONS

443. Lead Plaintiff will rely upon the presumption of reliance established by the fraud on the market doctrine as outlined in *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) ("*Basic*") and the presumption of reliance for omissions as outlined in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972) ("*Affiliated Ute*").

444. With respect to the *Basic* presumption, a presumption of reliance under the fraud on the market doctrine is appropriate because, among other things:

(a) Defendants made public misrepresentations and failed to disclose material facts during the Class Period;

(b) the misrepresentations and omissions were material;

(c) the Company's common stock traded in an efficient market;

(d) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Lead Plaintiff and other members of the Proposed Class purchased Vanda common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

445. At all relevant times, the market for Vanda common stock was efficient for the following reasons, among others:

(a) Vanda common stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient, electronic stock market;

(b) as a regulated issuer, Vanda filed periodic public reports with the SEC and the NASDAQ;

(c) Vanda regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Vanda was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of

their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

446. As a result of the foregoing, the market for Vanda common stock promptly digested current information regarding Vanda from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Vanda common stock during the Class Period suffered similar injury through their purchase of Vanda common stock at artificially inflated prices and a presumption of reliance applies.

447. In addition to the *Basic* presumption, a class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute* because the claims of the Proposed Class are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding Vanda's central business operations – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

COUNT I

For Violations of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

448. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

449. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and/or failed to disclose material facts

necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

450. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Vanda common stock during the Class Period.

451. Lead Plaintiff and the Proposed Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Vanda common stock. Lead Plaintiff and the Proposed Class would not have purchased Vanda common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and/or omissions.

452. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Proposed Class suffered damages in connection with their purchases of Vanda common stock during the Class Period.

COUNT II

For Violations of §20(a) of the Exchange Act
Against the Individual Defendants

453. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

454. The Individual Defendants acted as controlling persons of Vanda within the meaning of Section 20(a) of the Exchange Act as alleged herein. By reason of their positions as officers and/or directors of Vanda, the Individual Defendants had the power and authority to cause Vanda to engage in the wrongful conduct complained of herein. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiff as a Class Representative under Rule 23 of the Federal Rules of Civil Procedure, and appointing Lead Counsel as Class Counsel;

B. Awarding compensatory damages in favor of Lead Plaintiff and the Proposed Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiff and the Proposed Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding Lead Plaintiff and the Proposed Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Lead Plaintiff demands a trial by jury.

DATED: July 23, 2019

ROBBINS GELLER RUDMAN
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SAMUEL H. RUDMAN
DAVID A. ROSENFELD
MICHAEL G. CAPECI

/s/ Michael G. Capeci
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Lead Counsel for Lead Plaintiff

CERTIFICATE OF SERVICE

I, Michael G. Capeci, hereby certify that on July 23, 2019, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ Michael G. Capeci
MICHAEL G. CAPECI